

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

-----X	
SECURITIES AND EXCHANGE COMMISSION,	:
	:
Plaintiff,	:
	:
v.	:
	:
BIOVAIL CORPORATION, EUGENE MELNYK,	:
BRIAN CROMBIE, JOHN MISZUK, and KENNETH	:
HOWLING,	:
	:
Defendants.	:
	:
-----X	:

**DECLARATION OF SHAWN J. CHEN IN SUPPORT OF DEFENDANT
BRIAN CROMBIE'S MOTION TO DISMISS UNDER FED. R. CIV. P. 9(b) OR, IN THE
ALTERNATIVE, FOR A MORE DEFINITE STATEMENT
UNDER FED. R. CIV. P. 12(e)**

I, Shawn J. Chen, declare the following to be true under penalty of perjury:

1. I am a member of the Bar of this Court and a partner of Cleary Gottlieb Steen & Hamilton LLP, attorneys for Defendant Brian Crombie. I submit this declaration in support of Defendant Brian Crombie's Motion to Dismiss under Fed. R. Civ. P. 9(b) or, in the Alternative, for a More Definite Statement under Fed. R. Civ. P. 12(e).
2. Attached hereto as Exhibit A is a true and correct copy of the Securities and Exchange Commission's complaint filed on March 24, 2008.
3. Attached hereto as Exhibit B is a true and correct copy of the Letter from Ernst & Young LLP to Mr. Brian Crombie, dated June 29, 2001.

4. Attached hereto as Exhibit C is a true and correct copy of the Letter from Mr. Brian Crombie to Mr. Stan Hull, dated June 19, 2003.

Dated: June 23, 2008

Respectfully submitted,

/s/ Shawn J. Chen

David M. Becker

Shawn J. Chen

CLEARY GOTTlieb STEEN & HAMILTON LLP

2000 Pennsylvania Avenue, N.W.

Washington, D.C. 20006-1801

Tel.: (202) 974-1500

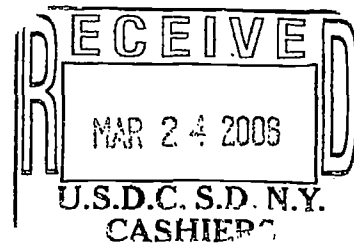
Fax: (202) 974-1999

Attorneys for Defendant Brian Crombie

JUDGE KAPLAN

08 CV 02979

MARK K. SCHONFELD
REGIONAL DIRECTOR
Attorneys for Plaintiff
SECURITIES AND EXCHANGE COMMISSION
New York Regional Office
3 World Financial Center
New York, NY 10281
(212) 336-1120



UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff,

-against-

BIOVAIL CORPORATION,
EUGENE N. MELNYK,
BRIAN CROMBIE,
JOHN MISZUK, and
KENNETH G. HOWLING,

Defendants.

08 Civ. ____
ECF CASE

COMPLAINT

Plaintiff Securities and Exchange Commission, for its Complaint against
Defendants Biovail Corporation ("Biovail" or the "Company"), Eugene N. Melnyk, Brian
Crombie, John Miszuk and Kenneth G. Howling (collectively, "Defendants"), alleges as follows:

SUMMARY OF ALLEGATIONS

1. This case involves chronic fraudulent conduct – including financial reporting
fraud and other intentional public misrepresentations – by Biovail Corporation, a Canadian

pharmaceutical company whose common stock is traded on the New York and Toronto stock exchanges. Obsessed with meeting quarterly and annual earnings guidance, Biovail's executives repeatedly overstated earnings and hid losses in order to deceive investors and create the appearance of achieving that goal. And, when it ultimately became impossible to continue to conceal the Company's poor performance, Biovail actively misled investors and analysts as to its cause. This corrupt strategy was employed by Biovail's most senior officers: Eugene Melnyk, former chairman and chief executive officer; Brian Crombie, former chief financial officer; John Miszuk, vice president, controller, and assistant secretary; and Kenneth G. Howling, current chief financial officer and former vice president of finance and corporate affairs.

2. The financial reporting fraud involves three accounting schemes that affected reporting periods from 2001 to 2003. They are: (1) a transaction through which Biovail, over several reporting periods in 2001 and 2002, improperly moved off its financial statements and onto the financial statements of a special purpose entity known as Pharmatech the expenses incurred in the research and development of some of Biovail's products that totaled approximately \$47 million through September 30, 2002 and related liabilities that exceeded approximately \$51 million through that date; (2) a fictitious bill and hold transaction that Biovail concocted to record approximately \$8 million in revenue in the second quarter of 2003; and (3) the intentional misstatement of foreign exchange losses that caused Biovail's second quarter 2003 loss to be understated by about \$3.9 million.

3. In addition, in October 2003, Biovail intentionally and falsely attributed nearly half of its failure to meet its third quarter 2003 earnings guidance to a truck accident involving a shipment of Biovail's product, Wellbutrin XL. Biovail intentionally misstated both the effect of

the accident on Biovail's third quarter earnings as well as the value of the product involved in the truck accident. The accident, in fact, had no effect on third quarter earnings.

4. Each of Biovail's fraudulent accounting schemes had a material effect on Biovail's financial statements for the relevant quarters and years and was engineered by Biovail's senior management in order to manage Biovail's earnings. In effecting these schemes, Biovail management also intentionally deceived its auditors as to the true nature of the transactions. The truck accident misstatements were intended to and did mislead analysts and the investing public concerning the significance of Biovail's failure to meet its own earnings guidance.

5. Biovail's then-chairman and chief executive, Eugene Melnyk, also violated share ownership disclosure provisions by failing to identify in his Schedule 13D filings his beneficial ownership of Biovail shares held by several trusts he settled in the late 1990s. Melnyk transferred the Biovail shares from his personal holdings to the trusts. However, because Melnyk continued to exercise both investment and trading authority over the shares in the trusts, Melnyk remained a beneficial owner of the securities and was under a legal obligation to disclose that ownership and material changes to it.

VIOLATIONS

6. By virtue of the foregoing conduct:
- a. Biovail, directly or indirectly, singly or in concert, has engaged in acts, practices, and courses of business that constitute violations of Section 17(a) of the Securities Act of 1933 (the "Securities Act") [15 U.S.C. § 77q(a)], Sections 10(b) 13(a), 13(b)(2)(A), and 13(b)(2)(B) of the

Securities Exchange Act of 1934 (the “Exchange Act”) [15 U.S.C. §§ 78j(b), 78m(a), 78m(b)(2)(A) and 78m(b)(2)(B)] and Rules 10b-5, 12b-20, 13a-1, and 13a-16, and Rule 302(b) of Regulation S-T [17 C.F.R. §§ 240.10b-5, 240.12b-20, 240.13a-1, 240.13a-16, and 232.302(b)].

- b. Melnyk, Crombie, Miszuk, and Howling, directly or indirectly, singly or in concert, have engaged in acts, practices, and courses of business that constitute violations of Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5].
- c. Crombie, directly or indirectly, singly or in concert, has engaged in acts, practices, and courses of business that constitute violations of Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)].
- d. Melnyk, directly or indirectly, singly or in concert, has engaged in acts, practices, and courses of business that constitute violations of Section 13(d) of the Exchange Act [15 U.S.C. § 78m(d)] and Rules 13d-1 and 13d-2 [17 C.F.R. §§ 240.13d-1 and 240.13d-2].
- e. Crombie and Miszuk, directly or indirectly, singly or in concert, have engaged in acts, practices, and courses of business that constitute violations of Section 13(b)(5) of the Exchange Act [15 U.S.C. § 78m(b)(5)] and Rules 13b2-1 and 13b2-2 [17 C.F.R. §§ 240.13b2-1 and 240.13b2-2].

- f. Crombie, directly or indirectly, singly or in concert, has engaged in acts, practices, and courses of business that constitute violations of Rule 13a-14 [17 C.F.R. § 240.13a-14].
- g. By virtue of the conduct described herein, Crombie and Miszuk are also each liable, pursuant to Section 20(e) of the Exchange Act, as an aider and abettor of Biovail's violations of Sections 10(b), 13(a), 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act [15 U.S.C. §§ 78j(b), 78m(a), 78m(b)(2)(A) and 78m(b)(2)(B)] and Rules 10b-5, 12b-20, 13a-1 and 13a-16 [17 C.F.R. §§ 240.10b-5, 240.12b-20, 240.13a-1 and 240.13a-16].

JURISDICTION AND VENUE

7. The Commission brings this action pursuant to the authority conferred upon it by Section 20(b) of the Securities Act [15 U.S.C. § 77t(b)] and Section 21(d)(1) of the Exchange Act [15 U.S.C. § 78u(d)(1)] seeking to restrain and permanently enjoin Biovail, Melnyk, Crombie, Miszuk, and Howling from engaging in the acts, practices, and courses of business alleged herein. The Commission also seeks a final judgment:

- a. ordering Biovail, Melnyk, Crombie, Miszuk, and Howling to disgorge any ill-gotten gains and to pay prejudgment interest thereon;
- b. ordering Biovail and Crombie to pay civil money penalties pursuant to Section 20(d) of the Securities Act [15 U.S.C. § 77t(d)];
- c. ordering Biovail, Melnyk, Crombie, Miszuk, and Howling to pay civil money penalties pursuant to Section 21(d)(3) of the Exchange Act [15 U.S.C. § 78u(d)(3)]; and

- d. permanently barring Melnyk, Crombie, Miszuk, and Howling from acting as an officer or director of any issuer that has a class of securities registered pursuant to Section 12 of the Exchange Act [15 U.S.C. § 78l] or that is required to file reports pursuant to Section 15(d) of the Exchange Act [15 U.S.C. § 78o(d)].

8. This Court has jurisdiction over this action pursuant to Section 22(a) of the Securities Act [15 U.S.C. § 77v(a)] and Sections 21(e) and 27 of the Exchange Act [15 U.S.C. §§ 78u(e) and 78aa].

9. Venue is proper under Section 22(a) of the Securities Act [15 U.S.C. § 77v] because a registered offering of Biovail's securities took place in, among other places, the Southern District of New York. Venue is proper under Section 27 of the Exchange Act [15 U.S.C. § 78aa] because certain of the transactions, acts, practices, and courses of business alleged in this Complaint took place in the Southern District of New York.

10. Biovail and Crombie, directly or indirectly, singly or in concert, have made use of means or instruments of transportation or communication in interstate commerce, or of the mails, in connection with the transactions, acts, practices, and courses of business alleged in this Complaint.

11. Biovail, Melnyk, Crombie, Miszuk, and Howling, directly or indirectly, singly or in concert, have made use of the means and instrumentalities of interstate commerce, or of the mails, or of a facility of a national securities exchange, in connection with the transactions, acts, practices, and courses of business alleged in this Complaint.

THE DEFENDANTS

12. **Biovail Corporation**, a foreign private issuer, is a pharmaceutical company incorporated under the laws of Ontario, Canada. Its headquarters are in Mississauga, Ontario, and it has facilities in the United States, Canada, Ireland, and Puerto Rico. As a foreign private issuer, Biovail files annual reports on Form 20-F and furnishes interim financial statements to the Commission on Form 6-K. During the relevant time period, Biovail included in its annual and interim reports financial statements purportedly prepared in accordance with both U.S. and Canadian generally accepted accounting principles. Since 2006, Biovail has been providing financial statements prepared only in accordance with U.S. generally accepted accounting principles ("U.S. GAAP").

13. **Eugene Melnyk**, age 48, is a Canadian citizen and a resident of St. Philip, Barbados. Melnyk is the founder of Biovail and served as its chairman and as a director from March 1994 through June 2007. From December 2001 to October 2004, Melnyk also was Biovail's chief executive officer. Melnyk resigned as a director and chairman of Biovail effective June 30, 2007.

14. **Brian Crombie**, age 47, is a Canadian citizen and a resident of Mississauga, Ontario. He was Biovail's chief financial officer from May 2000 to August 2004. In August 2004, Crombie was removed as chief financial officer and became Biovail's senior vice president for strategic development. As of May 2007, Crombie no longer holds any position with the Company.

15. John Miszuk, age 54, is a Canadian citizen and a resident of Mississauga, Ontario. He was in 2003, and is now, a vice president, controller, and assistant secretary of Biovail.

16. Kenneth G. Howling, age 49, is a U.S. citizen and a resident of Toronto, Ontario. On December 6, 2006, the Company announced Howling's promotion to his current position of senior vice-president and chief financial officer. He also was the Company's chief financial officer from 1997 to 2000. From 2000 to 2003, he was Biovail's vice president of finance, and in 2003 he assumed additional responsibilities for external communications to investors and analysts when his title changed to vice president, finance and corporate affairs. He is a certified public accountant licensed in New Jersey, but is not a Canadian chartered accountant.

FACTS

A. Misrepresentations Concerning the October 2003 Truck Accident

17. On September 30, 2003, a truck carrying a shipment of a Biovail product, Wellbutrin XL, left Biovail's Steinbach, Manitoba, plant bound for the North Carolina facility of a major international pharmaceutical company that distributed the product (the "Distributor"). On October 1, 2003, while en route to North Carolina, the truck was involved in a multi-vehicle traffic accident on a highway in Illinois.

18. The value of the product on the truck that was involved in the accident was about \$5 million.

19. Biovail, Melnyk, Crombie, and Howling issued two press releases and made numerous other public statements declaring that the loss of revenue and income associated with the truck accident contributed significantly to Biovail's substantial revenue shortfall for the third

quarter of 2003 in the amount of \$10 million to \$20 million, or about 23% to 38% of the total announced revenue shortfall for the quarter.

20. The press releases and other repeated public statements were materially false and misleading. The truck accident had no impact on Biovail's financial results for the quarter, as Biovail, Melnyk, Crombie, and Howling knew or recklessly disregarded. In addition, in the press releases and other public statements, Biovail, Melnyk, and Crombie grossly overstated the revenue value of the shipment involved in the truck accident.

The Truck Accident Had No Impact on Biovail's Third Quarter Revenues

21. Under U.S. GAAP, revenue may be recognized on the sale of a product like Wellbutrin XL when, among other things, delivery of the product by the seller to the buyer has occurred.

22. Pursuant to Biovail's agreement with the Distributor, all deliveries of Wellbutrin XL were subject to the term "F.O.B., [the Distributor's] facilities in the U.S.A. (freight collect)." This "F.O.B. Destination" delivery term meant that delivery occurred – and Biovail's revenue recognition would have been appropriate – only when the product reached the Distributor's facilities in the United States.

23. Under the FOB Destination shipping term – the term actually in effect – the truck accident had no impact on Biovail's third quarter financial results because the truck left Manitoba on September 30, which was too late for it to reach the Distributor's North Carolina facility prior to the end of the quarter. Under those circumstances, Biovail could not have recognized revenue resulting from the shipment regardless of the accident.

24. The deliberate misrepresentations by Melnyk, Crombie, Howling, and Biovail were based on the false premise that the delivery term was “F.O.B. Biovail,” pursuant to which delivery would have occurred – and Biovail could have recognized the revenue from the sale – at the time the product left Biovail’s facility.

25. However, even if the shipping term were FOB Biovail, the truck accident would have had no impact on Biovail’s third quarter financial results because the title to the product – and the risk associated with the accident – would have passed to the Distributor as soon as the truck left Biovail’s Manitoba plant. Under those circumstances, Biovail could have recognized revenue resulting from the shipment regardless of the accident.

26. Nevertheless, Melnyk, Crombie, Howling, and Biovail repeatedly and falsely attributed the Company’s third quarter revenue shortfall to the truck accident.

The October 3 Press Release and Conference Call

27. On October 3, 2003, Biovail issued a press release announcing that its third quarter 2003 “revenues [would] be below previously issued guidance and will be in the range of \$215 million to \$235 million and earnings per share of \$0.35 to \$0.45.” The revenues were below the guidance the Company had issued in February 2003 by about \$45 million to \$65 million and the earnings per share range were below the February estimate by \$0.23 at both ends of the range. This was the first time that Biovail had ever failed to meet its quarterly guidance.

28. The October 3 release falsely attributed a significant part of the revenue shortfall to the truck accident: “Contributing significantly to this unfavorable variance was the loss of revenue and income associated with a significant in-transit shipment loss of Wellbutrin XL as a

result of a traffic accident.” This statement was materially false and misleading, as Melnyk, Crombie, Howling, and Biovail knew or recklessly disregarded.

29. The October 3 press release also grossly overstated the revenue value of the Wellbutrin XL shipment involved in the accident: “Revenue associated with this shipment is in the range of \$10 to \$20 million.” This statement was materially false and misleading, as Melnyk, Crombie, and Biovail knew or recklessly disregarded.

30. The October 3 press release was issued by Howling’s office under his supervision and his name appears on it as the contact person. Beginning on October 2, Melnyk, Crombie, and Howling worked together on drafting the materially false and misleading October 3 press release. Howling drafted the release based on information he received from the others, including an initial draft press release that Crombie had prepared earlier in the day on October 2 and forwarded to both Melnyk and Howling. Crombie’s initial draft set forth the actual delivery term (*i.e.*, F.O.B. Destination) and stated correctly that the revenue from the product involved in the truck accident could not be recognized in the third quarter.

31. Despite the correct statements in Crombie’s initial draft, the October 3 release prepared by Howling, reviewed and edited by Melnyk and Crombie, and issued by the Company was false and misleading in that it stated that the truck accident contributed significantly to the third quarter revenue shortfall.

32. Although Crombie knew that the true value of the product on the truck involved in the accident was approximately \$5 million, he provided Howling with a falsely inflated valuation of \$10 to \$20 million for Howling to include in the press release.

33. Melnyk, Crombie, and Biovail knew or recklessly disregarded that the statement in the October 3 press release concerning the value of the product involved in the truck accident was materially false and misleading.

34. Later on October 3, Melnyk, Crombie, and Howling participated in a conference call with analysts in which Melnyk falsely stated: "This accident will have a negative financial impact on Biovail's third quarter revenues." Melnyk later in the call said again, "It is a third quarter item." Melnyk, Crombie, Howling, and Biovail knew or recklessly disregarded that these statements by Melnyk were materially false and misleading.

35. On the same conference call, Crombie falsely said, "The unfortunate incident . . . will have a material negative effect on Biovail's third quarter revenue and earnings." He also falsely told the analysts on the call, "Our contract with [the Distributor] has title change in Manitoba when it leaves our shipping dock." In fact, as Melnyk, Crombie, and Howling knew or recklessly disregarded, title to the product would change only upon arrival at the Distributor's facility in the United States, and therefore Biovail could not have recognized third quarter revenue on the shipment even if the accident had not occurred.

36. On the same call, Crombie referred to the value of the shipment as "\$15 million to \$20 million" – three to four times the actual revenue value. He also noted, "As a result of this accident, Biovail currently estimates that its total third quarter revenues from Wellbutrin XL will now be below \$10 million." Melnyk, Crombie, and Biovail knew or recklessly disregarded that these statements were materially false and misleading.

37. Howling participated in the conference call on October 3, 2003 and helped prepare the script for it. Although he knew or recklessly disregarded that the truck accident had

no impact on the Biovail's third quarter financial results, he remained silent during the call and did not correct any of the materially false and misleading statements that Melnyk and Crombie made during the call claiming that the accident did have such an impact.

The October 8 Press Release

38. On October 8, 2003, an investment bank research analyst issued a research report with a Biovail sell rating (the "Report"). In the Report, the analyst questioned both Biovail's valuation of the product lost due to the accident as well as the Company's assertion of when title to the product transferred.

39. Howling received a copy of the Report on October 8 and he promptly forwarded to Melnyk and Crombie the portion of the Report questioning the value of the shipment involved in the truck accident, suggesting that someone in finance draft responses to the issues raised. Soon after, Howling forwarded the entire Report to Melnyk and Crombie.

40. Following circulation of the Report, other research analysts asked Howling many questions about the quantity of product on the truck, the value of that product, and the wide range of value Biovail had given on October 3.

41. Also on October 8, an employee at the Distributor called and emailed Howling in order to correct some of the misstatements in the October 3 press release and conference call. The email, which Howling forwarded to Melnyk and Crombie, said that Biovail's conference call statement on when title to the product passed to the Distributor was "an incorrect statement, as the [agreement between Biovail and the Distributor] provides that title to and risk of loss with respect to the product would not have passed to [the Distributor] until the product was delivered to [the Distributor's] facility in the U.S.A."

42. Hours later – while under fire from analysts and investors as a result of the Report – Biovail issued a second press release that announced the recovery and salability of the product involved in the accident and “re-confirm[ed] that the sales value of these goods is within previously stated guidance.” Melnyk dictated the October 8 press release, which both Crombie and Howling reviewed and edited prior to its issuance. The October 8 press release was issued by Howling’s office under his supervision and his name appears on it as the contact person.

43. The October 8 press release was deliberately and materially false and misleading. Even though Melnyk, Crombie, Howling, and Biovail all knew or recklessly disregarded that the truck accident had no impact on third quarter revenues, the October 8 press release was silent on that subject. This was a material omission.

44. Moreover, Melnyk, Crombie, and Biovail knew or recklessly disregarded that the statement in the October 8 press release reconfirming the October 3 guidance concerning the value of the product involved in the accident was materially false and misleading because they knew that the value in the October 3 press release was deliberately overstated.

October 10-15 Road Show

45. In the days immediately following October 8, there was a perception inside Biovail that management’s credibility had been attacked by the Report on October 8. Biovail wanted to address these credibility concerns and other issues with investors, including any questions about Biovail’s ability to meet anticipated market demand for Wellbutrin XL.

46. To this end, on October 10, 13, 14, and 15, 2003, Biovail executives Melnyk, Crombie, and Howling conducted a road show in New York, Boston, and other cities to meet

with market analysts and investors. During the road show, the Biovail executives talked about, among other things, the matters discussed in the Company's October 3, 2003 press release.

47. The road show presentation included slides that repeated falsely that the truck accident's impact on Biovail's third quarter 2003 revenue was \$10 to \$20 million. In addition to the slides, the executives at the road show provided commentary reiterating the false statements in the October 3 press release. At the time of these misstatements, Melnyk, Crombie, Howling, and Biovail all knew or deliberately disregarded that the statements attributing part of the third quarter revenue shortfall to the truck accident were materially false and misleading. Melnyk, Crombie, and Biovail also knew or recklessly disregarded that the road show statements concerning the value of the product on the truck were materially false and misleading.

The Misstatements Were Never Fully Corrected

48. On March 3, 2004, in its annual earnings release Biovail finally acknowledged that the revenue associated with the product involved in the truck accident was only about \$5 million rather than the \$10 to \$20 million previously stated on October 3, 2003. Even this release, however, did not acknowledge that the truck accident had no impact on Biovail's third quarter revenues.

B. Material Misstatements Related to Pharmatech

49. In mid-2001, Biovail sought to increase net income by removing from its books the research and development costs associated with a key mid-term product pipeline. To achieve this goal, Biovail created a special purpose entity, Pharmaceutical Technologies Corp. (known as Pharmatech), to carry those costs.

50. And despite the fact that research and development costs were expected to be in the tens of millions of dollars, with some estimates as high as \$120 million, Pharmatech's sole shareholder, whom Biovail secured, invested only \$1 million in the company, of which \$350,000 was immediately refundable as a fee.

51. Biovail secured financing for Pharmatech from its own lender (the "Bank"), based on Crombie's assurances that, if at any time the Bank chose not to renew the Pharmatech financing, Biovail would likely purchase Pharmatech and retire the debt.

52. Crombie and Biovail deliberately and fraudulently orchestrated the Pharmatech arrangement as a means fraudulently to avoid recording on Biovail's books and records and reporting on its financial statements the expenses and liabilities related to the research and development of certain Biovail products. Crombie knew, and told the Bank, that it was probable that Biovail would repay Pharmatech's debt to the Bank when it first came due after one year, regardless of the outcome of the research and development at that point, if the Bank did not renew the financing. Crombie and Biovail understood that under those circumstances U.S. GAAP required Biovail to record Pharmatech's expenses and liabilities related to Pharmatech's research and development of the products and to include them on its own financial statements.

53. Nevertheless, Crombie and Biovail deliberately did not recognize and record Pharmatech's liabilities or charge its research development costs to expense as incurred on Biovail's books and records and did not include them on Biovail's financial statements. Instead, Crombie intentionally misled Biovail's auditors as to the true nature of the arrangement in order to secure from the auditors an opinion letter supporting Biovail's accounting for the arrangement.

The Applicable Accounting Principles

54. The applicable U.S. GAAP guidance in Statement of Financial Accounting Standards No. 68, *Research and Development Arrangements* ("SFAS 68"), provides that an enterprise that is a party to a research and development arrangement that allows it to obtain the results of research and development funded partially or entirely by others must estimate and recognize the liability on its own books and records if the enterprise is obligated to repay any of the funds provided by the other parties, regardless of the outcome of the research and development. Under such circumstances, SFAS 68 also requires the enterprise to charge the research and development costs to expense as incurred.

55. Even in the absence of a written agreement or contract requiring repayment by the enterprise, SFAS 68 sets forth a presumption that the enterprise has an obligation to repay the other parties if surrounding conditions suggest that it is probable that the enterprise will repay any of the funds regardless of the outcome of the research and development. That presumption can be overcome only by substantial evidence to the contrary. "Probable" in this context means that repayment is likely.

56. SFAS 68 provides examples of circumstances under which there is a presumption of a repayment obligation, including, among others, that the enterprise has indicated an intent to repay all or a portion of the funds provided regardless of the outcome of the research and development.

The Agreements Between Biovail and Pharmatech

57. Pharmatech was incorporated in Barbados on June 29, 2001 and, on the same day, it entered into a Product Development and Royalty Agreement with Biovail's Barbados

subsidiary, Biovail Laboratories, Inc. In this agreement, Pharmatech agreed to pay all the costs and expenses required to obtain regulatory approval of certain products in Biovail's midterm product pipeline, and Biovail granted Pharmatech a license to use the technologies necessary to develop the products.

58. Biovail also agreed to pay Pharmatech a royalty calculated as a percentage of the net sales of each successfully developed and approved product. Although the royalty payments would continue for ten years after each product's launch, Biovail could terminate the royalty obligation at any time upon thirty days notice and instead pay a contractually specified amount that increased over time depending on the date of the termination notice.

59. In a related Advisory Agreement, Biovail also agreed to guide Pharmatech in the development of the products.

60. The products included in the Pharmatech portfolio were those that could be launched within two to five years. The intention was to improve on drugs that were already in the market by providing new drug delivery formulations that could enhance effectiveness and increase patient compliance.

61. Several of the products were being developed to use controlled release technology that allowed for the gradual and predictable release of active ingredients over twelve or twenty four hours. Other products were to use the FlashDose drug delivery system, in which the product dissolves rapidly on the user's tongue.

62. Biovail had obtained the FlashDose technology in November 1999 by acquiring another pharmaceutical company for approximately \$250 million. That purchase was a significant acquisition and both the FlashDose and controlled release technologies were

important to Biovail. Although in June 2001, it was not certain that the FlashDose or controlled release technologies could be combined effectively and safely with any of the products in the Pharmatech portfolio, Biovail told the Bank that the products comprised its key mid-term product pipeline.

63. In connection with the agreement with Pharmatech, Biovail also entered into a Share Option Agreement with Pharmatech's sole stockholder. This agreement permitted Biovail to purchase all of the stockholder's Pharmatech shares at any time until December 31, 2006, in exchange for a fixed purchase price that ranged from \$1.25 million to \$5 million depending on the date Biovail exercised the share purchase option.

Pharmatech's Agreement with the Bank

64. Although Pharmatech agreed to pay the costs of developing the products, it had little working capital with which to do so. The sole stockholder's capital investment was just \$1 million and the new company had no sources of revenue and no assets other than the potential future royalty payments and the license from Biovail to use the FlashDose and controlled release technologies in developing the products.

65. To address this problem Crombie approached several potential lenders but ultimately only the Bank agreed to provide financing. Since the 1990's the Bank had served as Biovail's primary lender extending hundreds of millions of dollars in financing to Biovail through a credit facility.

66. In a June 29, 2001 agreement, the Bank agreed to extend credit to Pharmatech in the maximum aggregate amount of \$60 million for 364 days, at which time the outstanding debt would become due and payable. Pharmatech, however, could seek a 364-day extension of the

credit facility, which the Bank could grant or deny in its discretion. As collateral, Pharmatech granted the Bank a security interest in the Product Development and Royalty Agreement, including the potential future royalty payments and the license to use the crucial technology to develop the products. In the event of default, the Bank would also have the right to assign Pharmatech's rights under the agreement to a third party, including the right to continue development of the products using the FlashDose and controlled release technologies.

67. In connection with the financing, Biovail provided a comfort letter addressed to the Bank stating that, if Biovail exercised its share purchase option, Biovail would arrange to repay in full on or before June 30, 2004 any outstanding balance then due. Thus, the probability that Biovail would repay Pharmatech's debt to the Bank turned on the likelihood that Biovail would exercise its share purchase option if the Bank did not renew the loan after one year.

68. Crombie made clear to the Bank during the discussions about financing that Biovail probably would repay the Bank regardless of the outcome of the product development. Specifically, Crombie told the Bank that: (1) Biovail had a compelling business incentive to acquire Pharmatech and repay the loan because Biovail would want the royalties from any successfully developed products; (2) in any event, Biovail did not want its competitors acquiring access to the license to use the FlashDose (which Biovail had paid \$250 million to acquire) or controlled release technologies that Biovail had assigned to Pharmatech; and (3) the Bank had an effective "annual put" to Biovail, meaning that, when the credit facility came up for review after one year, if the Bank declined to extend the financing, the Bank could expect Biovail to acquire Pharmatech and repay the indebtedness.

The Auditors' Opinion Letter

69. In connection with the Pharmatech transaction, Biovail obtained from its auditors an opinion letter concerning the accounting implications of the transaction. Among other things, the opinion letter analyzed the deal in light of SFAS 68. The letter contains a table summarizing in one column the factors specified in SFAS 68 and in a parallel column the information Crombie provided to the auditors on each of those factors. Crombie knew that the auditors would rely upon that factual information in issuing their opinion, and they did rely on it.

70. Specifically, in order to secure the opinion letter from Biovail's auditors, Crombie made the following misstatements to the auditors:

- Crombie told the auditors that Biovail's management did not believe that it was probable that Biovail would repay the amounts being advanced and that the funding provided by others should not be recorded as a liability.
- Crombie told the auditors that Biovail had not provided any explicit or implicit undertakings to any parties involved in the transaction to repay all or a portion of the funds provided.
- Crombie told the auditors that Biovail's management did not currently believe that it was probable that it would choose to purchase the common shares of Pharmatech rather than incur any penalty.

71. Crombie's statements to the auditors were materially false and misleading. Crombie also omitted to tell the accountants what he was contemporaneously telling the Bank. In particular, Crombie failed to tell the auditors that he had told the Bank that in the event of a Pharmatech default, Biovail would have a compelling business incentive to exercise its option to acquire Pharmatech and repay the indebtedness to the Bank. Crombie also did not tell the auditors that he had told the Bank that the annual loan renewal mechanism was effectively an "annual put" to Biovail. Similarly, Crombie did not tell the auditors that he had told the Bank

that Biovail would not want to see the technology license in which the Bank had taken a security interest fall into the hands of Biovail's competitors. These were material omissions.

Biovail's Purchase of Pharmatech When the Bank Did Not Renew the Financing

72. At the conclusion of the initial year of financing, in June 2002, the Bank extended Pharmatech's financing but only for six more months, until December 31, 2002. As early as October 2002, Biovail management began to conclude that the Bank would neither renew the credit facility on December 31, 2002 nor increase its limit. Finally, on December 24, 2002, Crombie learned definitively that the Bank would not extend any additional funds to Pharmatech.

73. Three days later, Biovail sent a letter notifying the Pharmatech stockholder that Biovail intended to exercise the purchase option. Consistent with the "put" representations Crombie had made to the Bank, Biovail bought Pharmatech when the Bank decided not to extend additional financing, and repaid the Bank in full. Biovail's actions confirm that the Company's intention always was to exercise its purchase option and repay the Bank if the credit facility was not extended.

False and Misleading Public Filings

74. Biovail's interim financial statements for the quarter ended September 30, 2001 and for the nine months ended September 30, 2001 were furnished to the Commission on Form 6-K on November 13, 2001. Biovail's interim financial statements for the quarter ended March 31, 2002 were furnished to the Commission on Form 6-K on May 30, 2002. Biovail's interim financial statements for the quarter ended June 30, 2002 were furnished to the Commission on Form 6-K on August 29, 2002. On that date Crombie signed a certification stating the Form 6-K report "fairly presents, in all material respects, the financial condition and

results of operations of the Company.” Crombie and Biovail knew, or recklessly disregarded, that this representation was materially false and misleading.

75. Biovail’s interim financial statements for the quarter ended September 30, 2002 were furnished to the Commission on Form 6-K on November 25, 2002. On that date Crombie signed a certification stating the Form 6-K report “fairly presents, in all material respects, the financial condition and results of operations of the Company.” Crombie and Biovail knew, or recklessly disregarded, that this representation was materially false and misleading.

76. Biovail’s annual report for the year ended December 31, 2001 was signed by Crombie and filed with the Commission on Form 20-F on May 17, 2002. Biovail’s annual report for the year ended December 31, 2002 was signed by Crombie and filed with the Commission on May 20, 2003. On that date, Crombie also signed a certification stating that the Form 20-F report “fairly presents, in all material respects, the financial condition and results of operations of the Company.” Crombie and Biovail knew, or recklessly disregarded, that this representation was materially false and misleading.

77. As a direct result of Crombie’s and Biovail’s intentional failure to record on Biovail’s books and records a total of approximately \$47 million in Pharmatech’s expenses and more than approximately \$51 million in liabilities related to the research and development through September 30, 2002, Biovail’s financial statements were materially misstated. In addition, during the fourth quarter of 2002, Biovail did not charge to expense as incurred more than \$10 million in additional Pharmatech expenses and did not timely recognize and record on Biovail’s books and records additional related liabilities that Pharmatech incurred during that quarter.

78. Specifically, Biovail's financial reports were materially false and misleading in that they did not include Pharmatech's research and development expenses, causing: (1) net income to be overstated by approximately 50% in the third quarter 2001, 32% in the 2001 annual financial statements, 15% in the first quarter 2002, 18% in the second quarter 2002, and 16% in the third quarter 2002, and understated by approximately 17% in the 2002 annual financial statements; and (2) net income excluding certain charges to be overstated by approximately 25% in the third quarter 2001, 12% in the 2001 annual financial statements, 16% in the third quarter 2002, and 17% in the 2002 annual financial statements.

79. Biovail's balance sheets included in the financial reports also were materially false and misleading because they did not include Pharmatech's liability to the Bank, causing Biovail's total liabilities to be understated by approximately 2% in the third quarter 2001, 11% at year-end 2001, 5% in the first quarter 2002, 5% in the second quarter 2002, and 7% in the third quarter 2002.

80. Crombie and Biovail knew, or recklessly disregarded, that the financial statements identified above were materially false and misleading.

81. During the period when Biovail's financial statements were intentionally and materially misstated as a result of the Pharmatech fraud, Biovail conducted a registered offering in which it sold 12.5 million of its common shares and raised gross proceeds of approximately \$587.5 million. The prospectus supplement for this offering, filed on November 15, 2001, incorporated by reference Biovail's intentionally and materially false and misleading financial statements for the nine months ended September 30, 2001 furnished to the Commission on the Company's Form 6-K dated November 13, 2001.

82. Crombie and Biovail knew, or recklessly disregarded, that Biovail's materially false and misleading financial statements for the nine months ended September 30, 2001 were incorporated by reference into the prospectus supplement dated November 15, 2001.

C. A Sham Bill and Hold Transaction in June 2003

83. In the second quarter of 2003, both product revenue and total revenue were below even the low end of Biovail's previously issued guidance for the quarter, and the Company was in danger of missing earnings expectations for the first time in its history. Rather than acknowledge its poor performance that quarter, Crombie, Miszuk, and Biovail fraudulently and improperly recognized and recorded approximately \$8 million in additional revenue from a phony sale of Wellbutrin XL, a drug that analysts considered crucial to the Company's health. As a result, for the quarter ended June 30, 2003, Biovail's net loss was intentionally and materially understated by approximately 80% in its interim financial statements that Biovail furnished to the Commission on Form 6-K on August 29, 2003.

Biovail's Wellbutrin XL Agreement

84. Through subsidiaries, Biovail and the Distributor entered into a Development, License and CoPromotion Agreement in 2001. Pursuant to the agreement, and subject to FDA approval, Biovail was to manufacture Wellbutrin XL and sell it to the Distributor, which would distribute the product to third-party purchasers. The agreement required Biovail to produce Wellbutrin XL to be used for two purposes: (1) as sample product that Biovail would deliver in bulk to the Distributor and that the Distributor would package and distribute to physicians as a promotional tool; and (2) as trade product that Biovail would package in bottles labeled in

accordance with the FDA's requirements and that the Distributor would sell at a commercial price upon FDA approval.

85. As modified in December 2002, the agreement provided different prices for the differing dosages of sample product and trade product. Biovail sold sample pills to the Distributor at fixed prices per tablet, effectively at cost and, at the start of the product launch, at a loss. Biovail's Wellbutrin XL revenues for trade product were tied to the Distributor's net revenues from its sales to third parties. The agreement provided that Biovail would invoice trade product shipped to the Distributor at a fixed percentage of the Distributor's estimated net sales revenues and the invoicing percentage would rise as the Distributor's actual net sales increased over time. To the extent that the Distributor's estimate of its net sales revenues was different from the actual net sales revenue, the agreement contemplated a quarterly reconciliation process.

86. The FDA issued a letter on June 26, 2003 stating that Wellbutrin XL was "approvable," which meant that the FDA required further information before the new drug application could be approved. Among other things, the FDA's June 26 letter requested revised draft labeling for the product. The FDA did not finally approve Wellbutrin XL until August 29, 2003.

Biovail's Need to Generate Trade Product Revenue in June 2003

87. On February 7, 2003 Biovail published earnings guidance for its fiscal year 2003. It projected second quarter earnings per share between \$0.43 and \$0.50, third quarter earnings per share between \$0.58 and \$0.68, and annual sales of Wellbutrin XL of between \$75 million and \$150 million.

88. Wellbutrin XL was a key component of these earnings projections. It was widely expected that Wellbutrin XL would be the most significant product launch in the Company's history. The product, however, could not launch until it received FDA approval. When, by early June 2003, the FDA still had not yet approved Wellbutrin XL, Biovail executives became concerned because it was clear that Biovail would not meet its second quarter earnings projections unless it sold Wellbutrin XL trade product by June 30.

89. Although Biovail needed to produce prior to approval enough Wellbutrin XL trade product to enable the Distributor to launch the product promptly, it was risky to manufacture too many pills before the FDA had determined as part of the approval process what the product's shelf life would be because the Distributor could return stale pills to Biovail. Sample product, however, because it would be given away rather than sold, could be distributed up until expiration.

90. In April and May 2003 the Distributor submitted purchase orders for the delivery of Wellbutrin XL sample pills in June and for delivery of trade product (contingent on FDA approval of the trade product packaging) in July.

91. There were two reasons why the Distributor sought delivery of sample pills before trade pills: (1) under the agreement, the Distributor was responsible for packaging sample pills and wanted sufficient quantities on hand early so it could prepare for the launch; and (2) there was a risk that trade pills could expire unused if they were produced too early.

92. By the middle of June 2003, Biovail had not filled the Distributor's pending orders for sample product. At the time, Biovail was experiencing manufacturing problems and, as a result, was unable to manufacture sufficient quantities to fill the sample orders. In addition,

filling sample orders generated no income for Biovail. If Biovail had invoiced and shipped the inventory as samples during June, it would have sustained a loss because the cost of goods sold exceeded the contractual sample prices.

Crombie's Demand for a Trade Product Order in June

93. Even though Crombie knew about the production problems, he complained in a June 19, 2003 letter to the Distributor that Biovail needed the Distributor to place an order for trade product for June delivery "so that Biovail could be assured that it could book the revenue associated with those shipments [of trade product] in Q2 of 2003." He proposed in his letter to sell to the Distributor as trade product "all of our current production" of Wellbutrin XL.

94. The Distributor acquiesced in Crombie's demand for a June order for trade product in view of Biovail's threat to turn its manufacturing capacity to other products, since that could have caused a delay in the Wellbutrin XL launch.

95. On June 20, 2003, the Distributor placed an order for 27.1 million tablets of trade product. Since FDA approval was still pending, Biovail could not label the product so the Distributor agreed to let Biovail hold the product awaiting FDA approval and packaging. Although Biovail had not manufactured enough pills to meet the order, Biovail purported to earmark the entire then-existing inventory of Wellbutrin XL in its warehouse, approximately 18 million pills, to fill this "bill and hold" order.

96. On June 30, 2003, Biovail invoiced the Distributor approximately \$8 million for the product, and recorded a sale at a price that was slightly reduced from the usual trade prices to reflect that the packaging would not be done – or invoiced – until after FDA approval. The

parties did not agree, however, on a fixed schedule for delivery of the product because the date of FDA approval was not yet known.

Applicable Accounting Principles

97. Under U.S. GAAP, revenue may be recognized when it is realized or realizable and earned. Among other things, this requires that the seller's price to the buyer be fixed or determinable. With respect to the sale of a product like Wellbutrin XL, revenue may be recognized when delivery of the product by the seller to the buyer has occurred.

98. A legitimate bill and hold transaction permits revenue recognition absent delivery provided the following additional criteria under U.S. GAAP are met:

- (a) The risk of ownership must have passed to the buyer;
- (b) The customer must have made a fixed commitment to purchase the goods, preferably reflected in written documentation;
- (c) The buyer, not the seller, must request that the transaction be on a bill and hold basis. The buyer must have a substantial business purpose for ordering the goods on a bill and hold basis;
- (d) There must be a fixed schedule for delivery of the goods. The date for delivery must be reasonable and must be consistent with the buyer's business purpose (e.g., storage periods are customary in the industry);
- (e) The seller must not have retained any specific performance obligations such that the earnings process is not complete;
- (f) The ordered goods must have been segregated from the seller's inventory and not be subject to being used to fill other orders; and
- (g) The goods must be complete and ready for shipment.

99. The U.S. GAAP requirements for revenue recognition in general, including the fixed price requirement, and the additional requirements for a legitimate bill and hold

transaction, are summarized in Staff Accounting Bulletin No. 101 - *Revenue Recognition in Financial Statements*, which both Crombie and Miszuk reviewed at the time.

100. Although the bill and hold transaction was not genuine, one requirement in particular that was plainly and deliberately flouted was the requirement that the ordered goods must have been segregated from the seller's inventory and not be subject to being used to fill other orders. Indeed, the goods supposedly sold in the sham bill and hold transaction and segregated in the warehouse on June 30, were very soon thereafter designated by Miszuk and Crombie to fill the Distributor's pending orders for sample product and were shipped with new invoices at different and much lower prices – the sample prices.

The Pills Switch

101. Although no one knew prior to FDA approval what the expiration date for trade product would be, Crombie and Miszuk knew in June that all of the tablets then in Biovail's inventory – which were supposedly sold to the Distributor in the purported bill and hold transaction – were already at that time too old for trade use. To avoid potential returns of such stale pills by the Distributor, and in an attempt to fill the Distributor's orders for sample pills that had been pending since April, Crombie and Miszuk, no later than mid-July – before the close of Biovail's second quarter books – designated for shipment to the Distributor as sample product under sample invoices at the lower sample prices the very same pills that Biovail supposedly had designated and segregated for the purported on June 30 bill and hold transaction and for which Biovail had invoiced the Distributor at the higher contractual trade prices.

102. Crombie and Miszuk then invented a rationale by which Biovail purportedly could still recognize the trade sale revenue in the second quarter. They decided to replace the

pills that would now be shipped as sample pills at the lower sample prices with newer pills that would now become the subject of the June 30 sale. However, as of June 30, replacement pills did not exist because they had not yet been manufactured.

103. Crombie's and Miszuk's scheme was promptly implemented. By July 18 Biovail sent the Distributor various schedules showing that Biovail intended to ship to the Distributor under sample invoices and at the lower sample prices the very same pills that were the subject of the June 30 trade sale invoices at the higher, trade prices.

104. Crombie and Miszuk made their decision without conferring with Biovail's outside auditors and without telling them that the June 30 sale was a bill and hold transaction. Instead, Crombie and Miszuk led the auditors to understand that a trade shipment had actually occurred on June 30, which was not true. Miszuk also falsely told the auditors in connection with their quarterly review that pricing on the June 30 trade product sale was fixed even after he and Crombie had decided to ship the same pills supposedly sold in that transaction to the Distributor at the lower sample prices.

105. Moreover, in mid-July, when Miszuk and Crombie designated for shipment the purportedly segregated goods to fill the sample orders, Biovail still had not yet manufactured the additional pills that supposedly would replace them for the June 30 trade product sale. Thus, there were not sufficient pills in existence to apply to that sale once Crombie and Miszuk designated the purportedly segregated goods for shipment to fill the pending orders for sample pills.

Intentionally and Materially False and Misleading Public Statements

106. In late July, Biovail closed its books on the second quarter still recognizing improperly the approximately \$8 million in revenue in connection with the June 30 trade product sale. On July 29, 2003, Biovail issued an earnings release for the quarter ended June 30, 2003 that both Crombie and Miszuk reviewed before its issuance. On the same day, Biovail conducted a conference call with analysts to discuss the Company's financial results for the second quarter.

107. When Biovail closed its books for the quarter ended June 30, 2003 and when the Company announced its second quarter results on July 29, 2003, Crombie, Miszuk, and Biovail knew, or recklessly disregarded, that the requirements under U.S. GAAP for revenue recognition for a bill and hold transaction were not satisfied with respect to the Wellbutrin XL trade product sale transaction that purportedly occurred on June 30, 2003. Specifically, Crombie, Miszuk, and Biovail knew, or recklessly disregarded, among other things, that: (a) as of June 30, 2003 there was no fixed schedule for delivery of the goods; (b) the Distributor had not agreed to pay the higher prices for trade product if it was shipped and used as sample product; (c) the pills supposedly segregated for the June 30, 2003 trade sale comprised all of Biovail's Wellbutrin XL tablets as of June 30, 2003; and (e) no, or insufficient quantities of, other pills were existing, manufactured, and available as of June 30 or when Biovail's second quarter books were closed in July to replace the supposedly segregated pills once Crombie and Miszuk designated them for shipment to the Distributor to fill the Distributor's other pending orders for sample product at the lower sample prices.

108. As a direct result of the improper recognition of revenue on the phony bill and hold transaction, the July 29, 2003 earnings release was intentionally and materially false and misleading. Specifically, the earnings release understated the Company's net loss for the quarter by approximately 80% and overstated the company's net income (excluding acquired R&D) for the quarter by about 5%.

109. Biovail's announced earnings appeared to meet its earnings guidance for the second quarter.

110. Crombie participated in the conference call on July 29, 2003, during which Howling said, "Additionally, in the second-quarter 2003, approximately \$8 million of Wellbutrin XL was supplied to [the Distributor]." Although Crombie knew or recklessly disregarded at the time of the conference call that the requirements under U.S. GAAP for revenue recognition for the purported bill and hold transaction were not satisfied, he omitted to correct Howling's misstatement.

111. During August, after the Distributor began receiving the shipments of sample product, the Distributor notified Biovail that, because the August sample invoices identified the same tablets that were associated with the June 30 trade invoices, the Distributor would not process the June 30 trade invoices at that time. This message was forwarded to Crombie and Miszuk on August 14, 2003.

112. By no later than August 29, 2003, Miszuk, Crombie, and Biovail knew or recklessly disregarded, among other things, that during August the Distributor had refused to process the June 30 invoices for the trade product sale because Biovail was shipping the same pills under sample invoices at the lower sample prices.

113. Nevertheless, on August 29, 2003, the Company furnished to the Commission on Form 6-K Biovail's second quarter financial statements that were intentionally and materially false and misleading. Specifically, as a direct result of the improper recognition of revenue on the phony bill and hold transaction, the Company's net loss was understated by approximately 80%.

114. Miszuk signed this Form 6-K and Crombie also signed a statement that the Form 6-K report "fairly presents, in all material respects, the financial condition and results of operations of the Company." At this time, Crombie, Miszuk, and Biovail knew, or recklessly disregarded that the financial statements, and Crombie's statement, were intentionally and materially false and misleading because the revenue recognition on the purported June 30 trade product sale included in the second quarter financial statements was not in accordance with U.S. GAAP.

115. The next business day, on September 1, 2003, Biovail issued two credit memos to the Distributor voiding the two unpaid June 30 trade invoices.

116. On May 14, 2004, Biovail furnished to the Commission on Form 6-K/A restated financial statements for the quarter ended June 30, 2003. This restatement corrected material misstatements resulting from the previously unrecorded and unreported foreign exchange loss discussed below. But in this 2004 amendment, Biovail continued to reflect the approximately \$8 million in revenue and about \$4 million in earnings from the phony June 30 bill and hold transaction, causing the restated financial statements to understate net loss by about 45%. Miszuk signed this Form 6-K/A and Crombie also signed a statement that the Form 6-K/A report "fairly presents, in all material respects, the financial condition and results of operations of the

Company.” At that time, Crombie, Miszuk, and Biovail knew or recklessly disregarded that the financial statements, and Crombie’s statement, were materially false and misleading because the revenue recognition on the purported June 30 trade product sale included in the second quarter financial statements was not in accordance with U.S. GAAP.

117. Biovail’s annual report for the year ended December 31, 2003 was signed by Crombie and filed with the Commission on May 14, 2004. This report presents restated second quarter results as they appear in the Form 6-K/A furnished to the Commission the same day, and like that Form 6-K/A, these restated results continued to reflect the approximately \$8 million in revenue and about \$4 million in earnings from the phony June 30 bill and hold transaction, causing the restated financial results for the second quarter of 2003 set forth in the Form 20-F to understate net loss by about 45%. On May 14, 2003, Crombie also signed a certification stating, among other things, that, based on Crombie’s knowledge: (1) ‘this [Form 20-F] report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;’ and (2) ‘the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report[.]’ At this time, Crombie, Miszuk, and Biovail knew or recklessly disregarded that the Form 20-F, and Crombie’s statement, were materially false and misleading because the revenue recognition on the purported June 30 trade product sale and included in the second quarter financial statements was not in accordance with U.S. GAAP.

Crombie's and Miszuk's Deception of Biovail's Auditors

118. Not only did Biovail, Crombie, and Miszuk not seek advice and guidance from Biovail's auditors concerning whether the bill and hold accounting was proper, but Crombie and Miszuk also made material misstatements and omissions about the June trade order to the auditors in connection with both the second quarter review and the 2003 annual audit.

119. In connection with the quarterly review, by July 22, Miszuk told the auditors that pricing was fixed on the June trade order even though, by July 18, he and Crombie already had designated for shipment as sample pills – at the lower sample prices – the pills purportedly segregated for the bill and hold sale.

120. Also during the quarterly review, Crombie discussed with the auditors their request for a confirmation about fixed pricing. In their communications with Crombie and Miszuk during this time, the auditors referred to the June transaction as a “shipment,” showing their belief that actual delivery had occurred. Neither Crombie nor Miszuk corrected this misunderstanding. Similarly, neither Crombie nor Miszuk told the accountants in July that they had decided to use the pills originally identified on the “bill and hold” invoices to fill the Distributor's sample orders at the lower sample prices. They also did not tell the accountants that Biovail did not have sufficient product on hand to fill both the trade order and the outstanding sample orders, or even that the Company had treated the June trade product sale as a bill and hold transaction.

121. Miszuk and Crombie similarly failed to tell the auditors during August that the Distributor was refusing to pay the June invoices because Biovail had shipped to the Distributor the very same pills under sample invoices, that the available pills were aged and best used as

samples to avoid returns, and that the Distributor did not agree to pay trade prices if it used the pills as sample product. Crombie also falsely told the auditors in February 2004 during the year-end audit that the Distributor's non-payment of the invoices in connection with the June 2003 transaction was part of a larger problem involving the Distributor's failure to pay Biovail's invoices and had nothing to do with the specific bill and hold transaction.

122. Miszuk made additional misrepresentations in the management report, a report circulated to Biovail executives and auditors which purported to provide an overview of the Company's quarterly financial performance, including both narrative and financial statements. Prior to the circulation of the management report to Biovail's auditors on July 25 and 30, 2003, Miszuk reviewed and approved the content of the report, which he knew the auditors used as part of their review process. By including approximately \$8 million in revenue associated with the purported June 30 trade product sale, Biovail's July 25 and 30, 2003 second quarter 2003 management reports were materially false in two ways: (1) they overstated income and (2) both falsely asserted that "[a]ll figures contained in [the] report [were] in accordance with U.S. GAAP."

123. Only when the auditors again sought information concerning the transaction in January and February 2004 in connection with the year-end audit —after discovering the credit memos that reversed the June 2003 transaction — did the accountants first learn that Biovail had recorded the June 30 transaction as a bill and hold. Even then, neither Miszuk nor Crombie told the auditors that Biovail had shipped and invoiced as sample product in August the pills supposedly segregated for the bill and hold transaction in June.

124. Crombie and Miszuk also misled the auditors in early 2004 about the true reason for the September 1, 2003 credit memos. They told them that Biovail had credited out the old invoices so that it could issue new invoices that included packaging costs. The truth was that the Distributor had refused to pay the June 30 invoices and two sets of invoices could not have duplicate lot numbers on them.

D. Material Misstatements Concerning Unrecognized Foreign Exchange Loss

125. Concurrent with its improper attempt to record unearned revenue through the sham bill and hold transaction, Biovail also sought to conceal its weak second quarter 2003 performance by intentionally failing to record in the second quarter of 2003 approximately \$3.9 million in additional losses due to foreign currency fluctuations.

126. In December 2002 Biovail's Barbados subsidiary acquired from the Wellbutrin XL Distributor the Canadian rights to two pharmaceutical products. Biovail paid a portion of the consideration in cash and borrowed the balance from the Distributor. Although the currency for the transaction was Canadian dollars, Biovail's functional currency is the U.S. dollar, and Biovail reports its financial results in U.S. dollars.

127. The U.S. GAAP guidance applicable to the translation of foreign currency statements is Statement of Financial Accounting Standards No. 52, *Foreign Currency Translation*, which provides: "All elements of financial statements shall be translated by using a current exchange rate. For assets and liabilities, the exchange rate at the balance sheet dates shall be used." Consistent with this guidance, in its 2002 year-end financial statements filed with the Commission on Form 20-F on May 21, 2003, Biovail correctly reported the outstanding loan obligation in U.S. dollars by applying the then-current exchange rate.

128. On March 31, 2003, the date of Biovail's first quarter balance sheet, the Canadian dollar had strengthened against the U.S. dollar since December 31, 2002. Instead of applying the exchange rate current as of March 31 to translate the outstanding balance due on the loan from Canadian to U.S. dollars, Biovail translated the outstanding balance using the same exchange rate that it had applied in its financial statements for the year ended December 31, 2002. As a result, Biovail's financial statements for the first quarter of 2003, furnished to the Commission on Form 6-K on May 30, 2003, overstated net income by about 9%.

129. In Biovail's financial statements for the second quarter of 2003, the Company repeated the error it had made in the first quarter and again translated the remaining balance into U.S. dollars using the same exchange rate that Biovail had applied in its annual financial statements for the year ended December 31, 2002. This time, however, the error was not inadvertent.

130. On July 8, 2003, early in the quarterly closing process, the controller for the Barbados subsidiary and Biovail's senior director of legal accounting, both chartered accountants who reported to Miszuk, told Miszuk that the remaining outstanding balance should be adjusted to reflect the June 30 exchange rate and that doing so would generate an additional cumulative foreign exchange loss of approximately \$9 million.

131. Nevertheless, Miszuk and Biovail did not record the additional foreign exchange loss, whose recognition Miszuk knew, or recklessly disregarded, would negatively affect Biovail's second quarter financial results and require a restatement of the first quarter financial statements – something Miszuk did not want to do.

132. As a result, Biovail's interim financial statements for the quarter ended June 30, 2003, furnished to the Commission on Form 6-K on August 29, 2003, were materially misstated, intentionally or recklessly. Specifically, for the three-month period ended June 30, 2003, the Company's net loss was understated by about 80%, or approximately \$3.9 million, and for the six-month period ended June 30, 2003, the Company's net income was overstated by 18%, or approximately \$9.3 million. Although Miszuk knew about or recklessly disregarded the exchange rate translation error, he nevertheless signed this Form 6-K.

133. Miszuk also reviewed the July 25 and July 30 management reports and approved them for circulation to, among others, the Company's outside auditors during their second quarter review. These reports present results for both the three months and six months ended June 30, 2003. As a result of Biovail's failure to record correctly the foreign exchange loss, the three-month period is misstated in the reports by about \$3.9 million and the six-month period, which includes the misstatement for the quarter ended March 31, 2003, is misstated by approximately \$9.3 million. These reports also asserted falsely that all figures were in accordance with U.S. GAAP. Miszuk knew, or recklessly disregarded, that the financial statements in the management reports as well as that representation were materially false and misleading.

134. The problem continued into the third quarter of 2003 and resulted in an understatement of quarterly net income of about \$3.1 million, or 19%. For the nine months ended September 30, 2003, the resulting cumulative overstatement of net income was approximately \$6.2 million (the \$9.3 million overstatement for the first two quarters less \$3.1 million understatement in the third quarter), or about 9%.

135. In its March 3, 2004 year-end and fourth quarter 2003 earnings release, Biovail announced that, "in the course of preparing its financial statements for the fourth quarter and the full year 2003, the Company determined that U.S. GAAP requires that the Canadian dollar liability be translated at current rates." The release did not state that Miszuk and Biovail had learned about the issue the previous July.

136. On May 14, 2004, Biovail furnished to the Commission, on three Forms 6-K/A, its restated interim financial statements for the first, second, and third quarters of 2003. The restatements show that, as a result of the failure to record properly the foreign exchange loss, Biovail's net income was overstated by about 9% for the first quarter, its net loss was understated by 80% for the second quarter, and its net income was understated by about 19% for the third quarter.

137. Like the March 3 earnings release, each Form 6-K/A contained a statement implying that the error was discovered during the 2003 annual audit: "During the course of the preparation of its annual consolidated financial statements, the Company determined that it had applied an inappropriate exchange rate to a Canadian dollar denominated long-term obligation." Miszuk had learned about the problem much earlier, in July 2003, but on May 14, 2004 he nevertheless signed each of these Forms 6-K/A, which Biovail furnished to the Commission the same day.

138. The cumulative impact of the misstated foreign exchange loss and the improperly recognized bill and hold revenue was a total understatement of net loss in the second quarter 2003 financial statements by approximately 89%.

E. Melnyk Failed to Disclose his Full Biovail Share Ownership

139. As a holder of greater than 5% of Biovail's outstanding shares, Melnyk was under a legal obligation to make certain public disclosures concerning his stock ownership under Section 13(d) of the Exchange Act and related rules. On September 23, 1996, Melnyk settled four Cayman Island trusts and funded the trusts with Biovail shares that were previously held by him personally, directly or indirectly. The Biovail shares transferred to the trusts represented approximately 19% of the outstanding shares of Biovail at that time. Melnyk continued to exercise control over the Biovail shares in the trusts. Nevertheless, he did not include in his public filings pursuant to Section 13(d) of the Exchange Act and related rules any mention of his beneficial ownership of the Biovail shares in the trusts.

Melnyk Had a Beneficial Interest in the Shares Held in the Trusts

140. By 2003, the four trusts' holdings constituted just under eight percent of the Biovail common shares outstanding and approximately 30 percent of Melnyk's total Biovail holdings. Each of the four trusts had a "protector."

141. The controller of Biovail's Barbados subsidiary was separately paid by Melnyk to assist him with issues concerning the trusts, and assumed the role of protector of one of the trusts beginning in 2002. She also was a liaison between Melnyk and the trustees of all four trusts as well as the account representatives on the trusts' brokerage accounts. She conferred with Melnyk regularly about the trusts, including their transactions in Biovail securities.

142. Although the trust documents provide that trustees and the protective committees have investment power over trust assets, including the Biovail shares, Melnyk continued to make decisions concerning both the trusts and the shares they held.

143. Melnyk decided where the brokerage accounts for the trusts would be held – and hence where the Biovail stock would be held – and how that Biovail stock would be voted in Company elections. Melnyk similarly directed when and how the trusts would buy and sell Biovail stock.

144. In addition, Melnyk caused the trustees to sell Biovail stock to fund over \$100 million in loans to him from the trusts that he has never repaid. Melnyk knew or should have known that his requests for loans in certain circumstances could reasonably be expected to trigger sales by the trusts of Biovail securities.

145. Melnyk was aware of trading by the trusts in Biovail securities and he could, as a practical matter, exercise control over it and could have stopped it if he wished.

Melnyk Did Not Disclose His Ownership of the Trust Shares in any of his Filings Pursuant to Section 13(d) of the Exchange Act

146. As beneficial owner of more than 5% of the Biovail shares outstanding, Melnyk filed his first Schedule 13-D with the Commission on March 30, 1994. He has since filed twenty three amended Schedules 13-D through January 17, 2007. In none of these filings did he disclose his beneficial interest in the Biovail shares held by the trusts, or any material increases or decreases in the trusts' holdings.

F. Biovail's Violations of Rule 302(b) of Regulation S-T

147. Biovail electronically filed with the Commission certain annual reports on Forms 20-F. The Commission staff requested the Company to furnish to the staff manually signed signature pages or other documents in which the signatories to such electronic filings

acknowledged or otherwise adopted their signatures that appear in typed form within the electronic filings. The Company has not complied with that request and is unable to do so.

FIRST CLAIM FOR RELIEF
Violations of Section 17(a) of the Securities Act

148. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 147.

149. Crombie and Biovail, directly or indirectly, singly or in concert, in the offer and sale of securities, by the use of the means and instruments of transportation and communication in interstate commerce or by the use of the mails, directly and indirectly, have employed or are employing devices, schemes and artifices to defraud.

150. Crombie and Biovail, singly or in concert, in the offer and sale of securities, by the use of the means and instruments of transportation and communication in interstate commerce or by the use of the mails, directly and indirectly, have obtained or are obtaining money and property by means of untrue statements of material fact or omissions to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, and have engaged or are engaging in transactions, practices or courses of business which have operated or would operate as a fraud and deceit upon investors.

151. Crombie and Biovail, directly or indirectly, singly or in concert, in the offer and sale of securities described herein, have made untrue statements of material fact, or have omitted to state material facts. Among other things, the materially misleading statements or omissions pertained to Pharmatech's expenses and liabilities related to the research and development of certain Biovail products that Crombie and Biovail intentionally did not include on Biovail's

interim financial statements for the period ended September 30, 2001, which Biovail incorporated by reference into the prospectus supplement dated November 15, 2001.

152. Crombie and Biovail knew or were reckless in not knowing of the activities described above.

153. By reason of the foregoing, Crombie and Biovail have violated, and unless enjoined will again violate, Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)].

SECOND CLAIM FOR RELIEF
**Violations of and Aiding and Abetting Violations of Section 10(b) of the
Exchange Act and Rule 10b-5**

154. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 147.

155. Defendants, singly or in concert, in connection with the purchase and sale of securities, directly or indirectly, by the use of the means and instrumentalities of interstate commerce or of the mails, have employed or are employing devices, schemes and artifices to defraud; have made or are making untrue statements of material fact and have omitted or are omitting to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and have engaged or are engaging in acts, practices and courses of business which have operated or would operate as a fraud and deceit upon investors, in violation of Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5].

156. Defendants knew or were reckless in not knowing of the activities described above.

157. By reason of the foregoing, Defendants have violated, and unless enjoined will again violate, Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5].

158. By reason of the foregoing, Melnyk, Crombie, Miszuk, and Howling aided and abetted Biovail's violations of, and unless enjoined will again aid and abet violations of, Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5].

THIRD CLAIM FOR RELIEF
Violations of Section 13(b)(5) of the Exchange Act

159. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 147.

160. Crombie and Miszuk, directly or indirectly, singly or in concert, knowingly circumvented or knowingly failed to implement a system of internal accounting controls and knowingly falsified, directly or indirectly, or caused to be falsified books, records and accounts of Biovail that were subject to Section 13(b)(2)(A) of the Exchange Act [15 U.S.C. § 78m(b)(2)(A)].

161. By reason of the foregoing, Crombie and Miszuk have violated, and unless enjoined will again violate, Section 13(b)(5) of the Exchange Act [15 U.S.C. § 78m(b)(5)].

FOURTH CLAIM FOR RELIEF
Violations of Rule 13b2-1 of the Exchange Act

162. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 147.

163. Crombie and Miszuk, directly or indirectly, singly or in concert, falsified or caused to be falsified the books, records, and accounts of Biovail that were subject to Section 13(b)(2)(A) of the Exchange Act [15 U.S.C. § 78m(b)(2)(A)].

164. By reason of the foregoing, Crombie and Miszuk have violated, and unless enjoined will again violate, Rule 13b2-1 of the Exchange Act [17 C.F.R. § 240.13b2-1].

FIFTH CLAIM FOR RELIEF
Violations of Rule 13b2-2 of the Exchange Act

165. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 147.

166. Crombie and Miszuk were officers of Biovail at all relevant times.

167. As described above, Crombie and Miszuk, directly or indirectly, singly or in concert, made or caused to be made materially false or misleading statements, or omitted to state or caused another person to omit to state material facts necessary in order to make the statements made, in light of the circumstances under which such statements were made, not misleading to an accountant, in connection with (i) audits, reviews and examinations of the financial statements of Biovail required to be made pursuant to Commission regulations, and (ii) the preparation and filing by Biovail of documents and reports required to be filed with the Commission.

168. By reason of the foregoing, Crombie and Miszuk have violated, and unless enjoined will again violate, Exchange Act Rule 13b2-2 [17 C.F.R. § 240.13b2-2].

SIXTH CLAIM FOR RELIEF

**Violations of and Aiding and Abetting Violations of Section 13(a)
of the Exchange Act and Rules 12b-20, 13a-1, and 13a-16**

169. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 147.

170. Biovail did not file with the Commission such financial reports as the Commission has prescribed, and Biovail did not include, in addition to the information expressly required to be stated in such reports, such further material information as was necessary to make the statements made therein, in light of the circumstances in which they were made, not misleading, in violation of Section 13(a) and of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20, 13a-1, and 13a-16 [17 C.F.R. §§ 240.12b-20, 240.13a-1, and 240.13a-16].

171. By reason of the foregoing, Biovail violated, and Crombie and Miszuk have aided and abetted Biovail's violations of, Section 13(a) of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20, 13a-1, and 13a-16 [17 C.F.R. §§ 240.12b-20, 240.13a-1, and 240.13a-16].

SEVENTH CLAIM FOR RELIEF

**Violations of and Aiding and Abetting Violations
of Sections 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act**

172. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 147.

173. Biovail did not:

- a. make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflected the transactions and dispositions of its assets; and

- b. devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that:
 - i. transactions were executed in accordance with management's general or specific authorization;
 - ii. transactions were recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and to maintain accountability for assets;
 - iii. access to assets was permitted only in accordance with management's general or specific authorization; and
 - iv. the recorded accountability for assets was compared with the existing assets at reasonable intervals and appropriate action was taken with respect to any differences, in violation of Sections 13(b)(2)(A) and 13(B)(2)(B) of the Exchange Act [15 U.S.C. §§ 78m(b)(2)(A) and 78m(b)(2)(B)].

174. By reason of the foregoing, Biovail violated, and Crombie and Miszuk have aided and abetted Biovail's violations of, Sections 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act [15 U.S.C. §§ 78m(b)(2)(A) and 78m(b)(2)(B)].

EIGHTH CLAIM FOR RELIEF
Violations of Rule 13a-14

175. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 147.

176. Crombie knew or recklessly disregarded that his certifications of Biovail's 2002 and 2003 Forms 20-F were materially false and misleading.

177. By reason of the foregoing, Crombie has violated, and unless enjoined will again violate, Rule 13a-14 [17 C.F.R. § 240.13a-14].

NINTH CLAIM FOR RELIEF

Violations of Section 13(d) of the Exchange Act and Rules 13d-1 and 13d-2

178. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 147.

179. The common stock of Biovail at all relevant times was registered pursuant to Section 12 of the Exchange Act [15 U.S.C. § 78l].

180. Pursuant to Section 13(d) of the Exchange Act [15 U.S.C. § 78m(d)] and Rules 13d-1 and 13d-2 [17 C.F.R. §§ 240.13d-1 and 240.13d-2], persons who are directly or indirectly the beneficial owners of more than five percent of the outstanding shares of a class of voting equity securities registered under the Exchange Act are required to file a Schedule 13D within ten days of the date on which their ownership exceeds five percent, and to notify the issuer and the Commission of any material increases or decreases in the percentage of beneficial ownership by filing an amended Schedule 13D. The Schedule 13D filing requirement applies both to individuals and to two or more persons who act as a group for the purpose of acquiring, holding, or disposing of securities of an issuer.

181. As described above, Melnyk was at all relevant times a beneficial owner of more than 5 percent of Biovail's shares. In addition to the shares that he held in his own name, as a

result of his investment and voting authority over the shares held in the trusts, he also was a beneficial owner of those Biovail shares.

182. Melnyk and the trusts also were sufficiently interrelated that they constituted a group for the purposes of the Section 13(d) and the Schedule 13D filing requirement.

183. Accordingly, Melnyk was under an obligation to file with the Commission true and accurate reports with respect to his ownership of the Biovail shares held by the trusts and any material increases or decreases in the percentage of such ownership, pursuant to Section 13(d) of the Exchange Act [15 U.S.C. § 78m(d)] and Rules 13d-1 and 13d-2 [17 C.F.R. §§ 240.13d-1 and 240.13d-2]. He did not do so.

184. By reason of the foregoing, Melnyk violated and, unless enjoined, will again violate Section 13(d) of the Exchange Act [15 U.S.C. §78m(a)] and Rules 13d-1 and 13d-2 thereunder [17 C.F.R. §§ 240.13d-1 and 240.13d-2].

TENTH CLAIM FOR RELIEF
Violations of Rule 302(b) of Regulation S-T

185. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 147.

186. Biovail did not retain and has not produced to the Commission staff upon request manually signed signature pages or other documents authenticating, acknowledging, or otherwise adopting the signatures that appear in typed form within its electronic filings on Form 20-F.

187. By reason of the foregoing, Biovail has violated, and unless enjoined will again violate, Rule 302(b) of Regulation S-T [17 C.F.R. § 232.302(b)].

PRAYER FOR RELIEF

WHEREFORE, the Commission respectfully requests a Final Judgment:

I.

Permanently enjoining Crombie and Biovail, their agents, servants, employees, and attorneys and all persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)].

II.

Permanently enjoining Melnyk, Crombie, Miszuk, Howling, and Biovail, their agents, servants, employees, and attorneys and all persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5], and Melnyk, Crombie, Miszuk, and Howling from aiding or abetting future violations of Sections 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5].

III.

Permanently enjoining Biovail, its agents, servants, employees, and attorneys and all persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Sections 13(a) and 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act [15 U.S.C. §§ 78m(a) and 78m(b)(2)(A) and 78m(b)(2)(B)] and Rules 12b-20, 13a-1, and 13a-16 [17 C.F.R. §§ 240.12b-20, 240.13a-1 and 240.13a-16] and Rule 302(b) of Regulation S-T [17 C.F.R. § 232.302(b)].

IV.

Permanently enjoining Crombie and Miszuk, their agents, servants, employees, and attorneys and all persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Section 13(b)(5) of the Exchange Act [15 U.S.C. § 78m(5)] and Rules 13b2-1 and 13b2-2 [17 C.F.R. §§ 240.13b2-1 and 240.13b2-2], and from aiding and abetting future violations of Sections 13(a) and 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act [15 U.S.C. §§ 78m(a), 78m(b)(2)(A) and 78m(b)(2)(B)] and Rules 12b-20, 13a-1, and 13a-16 [17 C.F.R. §§ 240.12b-20, 240.13a-1 and 240.13a-16].

V.

Permanently enjoining Crombie, his agents, servants, employees, and attorneys and all persons in active concert or participation with him who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Rule 13a-14 of the Exchange Act [17 C.F.R. § 240.13a-14].

VI.

Permanently enjoining Melnyk, his agents, servants, employees, and attorneys and all persons in active concert or participation with him who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Section 13(d) of the Exchange Act [15 U.S.C. § 78m(d)] and Rules 13d-1 and 13d-2 [17 C.F.R. §§ 240.13d-1 and 240.13d-2].

VII.

Ordering Biovail, Melnyk, Crombie, Miszuk, and Howling to disgorge any ill-gotten gains from the conduct alleged herein and to pay prejudgment interest thereon.

VIII.

Imposing civil penalties upon Biovail and Crombie pursuant to Section 20(d) of the Securities Act [15 U.S.C. § 77t(d)] and upon Biovail, Melnyk, Crombie, Miszuk, and Howling pursuant to Section 21(d)(3) of the Exchange Act [15 U.S.C. § 78u(d)(3)].

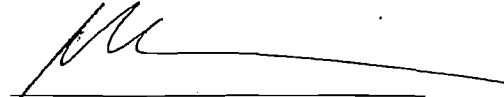
IX.

Permanently barring Crombie, pursuant to Section 20(e) of the Securities Act [15 U.S.C. § 77t(e)], and Melnyk, Crombie, Miszuk, and Howling, pursuant to Section 21(d)(2) of the Exchange Act [15 U.S.C. § 78u(d)(2)], from serving as an officer or director of any issuer that has a class of securities registered under Section 12 of the Exchange Act [15 U.S.C. § 78l] or that is required to file reports pursuant to Section 15(d) of the Exchange Act [15 U.S.C. § 78o(d)].

X.

Granting such other and further relief as to this Court seems just and proper.

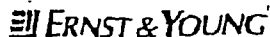
Dated: New York, New York
March 24, 2008



Mark K. Schonfeld
Regional Director
Attorneys for Plaintiff
SECURITIES AND EXCHANGE
COMMISSION
3 World Financial Center
New York, NY 10281-1022
(212) 336-1020

Of Counsel:

Andrew M. Calamari
Robert J. Keyes
Todd D. Brody
Celeste A. Chase
Catherine Smith



Ernst & Young LLP
Chartered Accountants
Ernst & Young Canada
P.O. Box 251, 222 Bay St.
Toronto, Ontario M5H 1Y7

Ernst & Young - 10000
10000 10000

June 29, 2001

PRIVATE AND CONFIDENTIAL

Mr. Brian Crombie
Senior Vice President and Chief Financial Officer
Biovail Corporation
2488 Dunwin Avenue
Mississauga, Ontario
L5L 1J9

Dear Mr. Crombie:

Re: Biovail Corporation and its subsidiaries ("Biovail") - Accounting
Implications of Pharmaceutical Technologies Limited ("PTL")

We have been engaged to report on the appropriate application of United States generally accepted accounting principles to the transaction described below. This letter is being issued to assist management to evaluate the accounting for the described transaction.

Transaction summary

Biovail is proposing to enter into a transaction, described in detail in the Transaction Summary attached as Appendix A, involving research and development to be conducted by PTL in exchange for a royalty interest with respect to a minimum of six of Biovail's current drug development opportunities. This letter is based on copies of draft agreements and other information that were provided to us by management of Biovail up to the date of this letter. If the final versions of the agreements differ from the information provided to us, our current advice with respect to the accounting implications may change.

The most significant terms of the transaction as currently understood by us are summarized below:

1. Biovail will not own any debt or equity securities of PTL.
2. All of the share capital of PTL (approximately \$1 million) will be owned by an unrelated group of third party investors.
3. PTL will continue the development of certain drug applications that had been previously identified by Biovail in return for a royalty interest in revenues that may be earned from the eventual regulatory approval and sale of any of the products included in the arrangement. Most of the products are in the early stages of research and development. Two of the products have reached Phase III clinical trials but development, regulatory and market risks continue to


A member of Ernst & Young International Ltd.

 ERNST & YOUNG

- 2 -

cause significant uncertainty as to whether these products ultimately will be approved and sold.

4. PTL's right to develop the specified products is exclusive to it while the product development and royalty agreement remains in force.
5. PTL will finance the proposed drug development program from a bank lending facility. The lending facility, which will aggregate approximately \$140 million once fully utilized, will be provided in three successive annual tranches of \$60 million, \$40 million and \$30 million respectively, based on the current project development plan. The proposed advances under the credit facility will be subject to annual approval by the lender. The lending facility will carry high interest rates (approximately 23%) reflecting the significant risk associated with the investment.
6. The only security available to PTL's lender will be PTL's royalty interests. However, in order to demonstrate to the lender that Biovail and PTL intend to work together with respect to the product development program, Biovail will provide an undertaking to the lender to not sell its PTL share and royalty options, to assume PTL's debt if the share option is exercised and to not amend the product development and royalty agreement without the lender's consent.
7. Biovail will retain the right but not the obligation to reacquire one of the product development opportunities, Tramadol, being developed by PTL. The option exercise price payable by Biovail is the greater of the estimated net present value of expected future royalties less future development costs or \$25 million. Biovail and PTL may also negotiate for the transfer of a product development opportunity other than Tramadol to Biovail but, in any event, only one of the six original products could be transferred under this option arrangement.
8. Biovail will have an option (but not an obligation) to acquire the equity of PTL for various amounts set out in the agreement starting at \$1.75 million on December 31, 2002 and increasing to \$5 million by December 31, 2006.
9. Biovail will have an option (but not an obligation) to acquire PTL's royalty interests at negotiated amounts beginning at \$50 million on December 31, 2001 and increasing to \$195 million by December 31, 2006.
10. PTL shareholders and lenders will not have any contractual or constructive right or ability to put PTL's shares or PTL's royalty interest to Biovail.
11. Biovail will provide advisory services to PTL for approximately \$400,000 per year.
12. PTL will have limited ability to conduct business other than the development

 ERNST & YOUNG

- 3 -

of the products stipulated in the development agreement. The owners of PTL will be unable to sell their shares, re-organize the company, sell the Company's assets, pay dividends, or incur additional indebtedness (without the agreement of BiovailTM) while the development agreement is in force

13. At the time of entering into the agreements, Biovail and PTL will not have made any firm arrangements regarding Biovail's role in conducting product development activities on behalf of PTL. However, Biovail will have the right of first refusal to conduct the product development and Biovail and PTL expect to negotiate product development contracts at a later date. Biovail is currently not able to perform a substantial portion of the research and development planned by PTL.
14. There will be no fixed time period within which PTL must complete the product development program. Should PTL's product development costs exceed those currently planned and PTL is unable to raise additional capital, the development effort may be resumed and completed by Biovail. In this event, if a product is approved and sold, PTL will receive royalties on a pro rata basis which recognizes the respective development costs assumed by the two parties.
15. Royalties will be payable to PTL based on the sale of any of the six products that are ultimately approved and sold, but only for the treatment of the indication specified by product in the agreement.
16. PTL will have the right to develop two additional product opportunities (at its own expense) that have been identified by Biovail if none of the six original products result in commercial applications. PTL will select these two additional opportunities from a list of four opportunities set out in the agreements. Biovail has not performed any significant research and development with respect to these four additional opportunities which, at this time, simply represent initial proposals for possible future development projects. As a result, Biovail estimates that the contingent product development opportunity provided to PTL currently has only a nominal fair value.
17. PTL intends to acquire \$10 million of manufacturing equipment for lease to Biovail. The terms of such lease have not yet been negotiated but it is expected that such lease will be on normal commercial leasing terms between unrelated lessors and lessees.
18. PTL's lender is also a lender to Biovail. All existing and presently contemplated business relationships between the lender and Biovail reflect normal commercial terms between unrelated parties.

© 2008 Ernst & Young Global Limited

ERNST & YOUNG

- 4 -

Issues

The issue is to determine the appropriate treatment for Biovail under accounting principles generally accepted in the United States for the transaction described above. There are two primary questions to be considered:

1. Should PTL be consolidated within Biovail?
2. Even if consolidation is not appropriate, should Biovail nonetheless account for the project development expenses and liabilities of PTL in its own financial statements?

Question One

Consolidation

Under ARB 51, consolidation is normally required when one party has a majority of the voting interest in another enterprise. Accordingly, under the described situation, Biovail would not normally consolidate PTL as it does not own any voting securities of PTL. There are, however, exceptions to this general rule, which must be considered.

EITF Topic D-14 provides guidance indicating that for non-consolidation to occur,

"the majority owner (or owners) of the SPE must be an independent third party who has made a substantive capital investment in the SPE, has control of the SPE and has substantive risks and rewards of ownership of the assets of the SPE. Conversely, SEC staff believes that non-consolidation and sales recognition are not appropriate by the sponsor or transferor when the majority owner of the SPE makes only a nominal capital investment, the activities are virtually all on the sponsor's or transferor's behalf and the substantive risks and rewards of the assets or the debt of the SPE rest directly or indirectly with the sponsor or transferor."

In this transaction, the majority owners of PTL have made more than a nominal investment (\$1 million) in a company whose only asset is a royalty interest in products that will require an additional \$140 million to be spent to complete research and development before reaching commercial production. The debt to be incurred to finance future research and development activities will be provided by third party lenders who have no guarantee from Biovail so the existence of this debt further dilutes the position of the common shareholders if the results of the product development are less than anticipated. Further, the option to assume control of PTL represents a significant decision for Biovail to make. In addition to the \$1.75 million need to acquire the common shares, Biovail would also need to assume approximately \$140 million of debt in the acquisition. This debt amount is significant to Biovail considering that Biovail could choose to pay

Ernst & Young LLP

ERNST & YOUNG

- 5 -

the royalties if it believes that this would be ultimately more economic than repaying any assumed debt. All of these factors support non-consolidation.

Conversely, it can be argued that the activities of PTL are being conducted on behalf of Biovail as Biovail has retained the rights to manufacture and sell any products. However, the PTL owners and lenders know that they are incurring costs in return for a royalty interest in these products. Accordingly the value, risks and rewards of their assets (the royalty interest) and liabilities (the bank lending facilities), while closely aligned with Biovail, do not rest solely with Biovail and do not indicate that consolidation is required.

Since there are arguments that support both consolidation and non-consolidation, there is significant judgment involved in the determination of the appropriate accounting. In our opinion, consolidation is not required given the facts and circumstances described in this letter.

Question Two

Research and Development Arrangements

Further guidance on how to account for this transaction is also contained in FAS 68 which relates to the appropriate accounting for research and development arrangements. In order to determine the appropriate accounting for the funds expended by PTL on product development, one needs to consider whether Biovail is obligated to repay any amounts paid by others for performing the work. There are a number of factors to be evaluated which are specified in paragraphs 6, 7 and 8 of FAS 68 and which are summarized below:

FAS 68 discussion	Application to these facts
6. To conclude that a liability does not exist, the transfer of the financial risk involved with research and development from the enterprise to the other parties must be substantive and genuine. To the extent that the enterprise is committed to repay any of the funds provided by the other parties regardless of the outcome of the research and development, all or part of the risk has not been transferred. The following are some examples in which the enterprise is committed to repay:	You have informed us that there are no contractual guarantees of Biovail or any parties related to Biovail to acquire the common shares of PTL or to repay any funds used to continue the research and development of the products under development by PTL.

© 2008 Ernst & Young LLP

ERNST & YOUNG

- 5 -

<p>a. The enterprise guarantees, or has a contractual commitment that assures, repayment of the funds provided by the other parties regardless of the outcome of the research and development.</p> <p>b. The other parties can require the enterprise to purchase their interest in the research and development regardless of the outcome.</p> <p>c. The other parties automatically will receive debt or equity securities of the enterprise upon termination or completion of the research and development regardless of the outcome.</p>	
<p>7. Even though the written agreements or contracts under the arrangement do not require the enterprise to repay any of the funds provided by the other parties, surrounding conditions might indicate that the enterprise is likely to bear the risk of failure of the research and development. If those conditions suggest that it is probable that the enterprise will repay any of the funds regardless of the outcome of the research and development, there is a presumption that the enterprise has an obligation to repay the other parties. That presumption can be overcome only by substantial evidence to the contrary.</p>	<p>You have informed us that management does not believe that it is probable that it will repay the amounts being advanced and that the funding provided by others should not be recorded as a liability.</p> <p>Some of the factors that should be considered are discussed below.</p>
<p>8. Examples of conditions leading to the presumption that the enterprise will repay the other parties include the following:</p> <p>a. The enterprise has indicated an intent to repay all or a portion of the funds provided regardless of the outcome of the research and development.</p>	<p>It is our understanding that Biovail has not provided any explicit or implicit undertaking to any parties involved in the transaction to repay all or a portion of the funds provided.</p>


Ernst & Young LLP

ERNST & YOUNG

- 7 -

<p>b. The enterprise would suffer a severe economic penalty if it failed to repay any of the funds provided to it regardless of the outcome of the research and development. An economic penalty is considered "severe" if in the normal course of business an enterprise would probably choose to pay the other parties rather than incur the penalty. For example, an enterprise might purchase the partnership's interest in the research and development if the enterprise had provided the partnership with proprietary basic technology necessary for the enterprise's ongoing operations without retaining a way to recover that technology, or prevent it from being transferred to another party, except by purchasing the partnership's interest</p>	<p>This is an area of significant management judgment. Although PTL will have a royalty interest in the products to be developed, it does not and will not own any "core technology". Accordingly, a decision to not acquire PTL would not represent a significant economic penalty to Biovail. If the products are successful, Biovail could simply manufacture and market the products and pay the royalty and still obtain a reasonable profit from its efforts. Accordingly, it is our understanding that management does not currently believe that it is probable that it would choose to purchase the common shares of PTL rather than incur any penalty.</p>
<p>c. A significant related party relationship between the enterprise and the parties funding the research and development exists at the time the enterprise enters into the arrangement.</p>	<p>There is currently no related party relationship between the parties funding the research and Biovail</p>
<p>d. The enterprise has essentially completed the project before entering into the arrangement.</p>	<p>The technology being developed for PTL is still in various stages of clinical trials and therefore is not complete. Accordingly the initial funds received from the lender would not be the subject of this rule.</p> <p>However, the structure of the lending arrangement, whereby the lender makes annual decisions on additional tranches of funding each year, could put subsequent funding in a different category. If any of the projects are essentially complete and approved by the FDA, then it may be argued that funding provided after this date could be considered differently than the initial funding. We would need to review the facts and circumstances each time a new tranche of financing was received.</p>

Ernst & Young LLP

 ERNST & YOUNG

- 8 -

Based upon all of the above, it is our opinion that Biovail's recording PTL's project development expenses and liabilities in its own financial statements is not required at this time.

The ultimate responsibility for the appropriate application of generally accepted accounting principles for the transactions described above rests with your management as preparers of the financial statements. Our judgment on the appropriate application of generally accepted accounting principles for the transactions described above is based on the facts, circumstances and assumptions provided to us and as summarized in this letter. Should there be any changes or omissions to the facts, circumstances and assumptions set out in this letter, such changes or omissions could have the effect of changing our opinion.

Furthermore, our conclusion represents our judgment regarding the application of generally accepted accounting principles and the published rules and regulations of the Securities and Exchange Commission in the United States (the "SEC"). Our conclusion is not binding on the SEC or its staff, and there is no assurance that the SEC or its staff will not successfully assert a contrary position.

It is understood that this letter is to be made available solely to the management of Biovail and is not to be referred to or distributed to any other party without our prior written consent.

Yours sincerely,

Ernst & Young LLP

Robert C. Scullion/Douglas L. Cameron
416-943-2549/416-943-3665

© A MEMBER OF ERNST & YOUNG INTERNATIONAL, LLC

CONFID TRTMNT UNDER FOIA REQ

B 19200

Appendix A

1. Introduction

Biovail is sponsoring the formulation of an R&D vehicle that will be owned by third party investors and financed with bank debt. This confidential information memorandum describes the proposed transaction, the structure of the vehicle, the products to be developed by the R&D vehicle and the economics. Biovail is soliciting commitments for debt and equity participation in the vehicle.

Biovail is a fully integrated international pharmaceutical company applying advanced proprietary controlled-release drug delivery technology to the development of superior branded and cost effective generic formulations of medications for the treatment of chronic medical conditions. It is engaged in all stages of pharmaceutical development, from research and development, through clinical testing and regulatory filings to full scale manufacturing.

Biovail markets its products in North America, Europe and more than 50 countries through strategic partnerships and licensing agreements with many of the world's leading pharmaceutical companies. Biovail also markets products directly through its sales and marketing division, Crystaal in Canada and Biovail Pharmaceuticals in the United States, and provides independent clinical and laboratory services to the pharmaceutical industry through its Contract Research Division.

Biovail has executed three significant strategic initiatives during the past eighteen months, investing in excess of \$750MM. These initiatives have strengthened Biovail's technological base, expanded its sales and marketing operations into the US market and doubled its size with the number one brand in the cardiovascular therapy market. In late 1999, Biovail acquired Fuisz Technologies with its Flash Dose and Taste Masking technology. In October 2000, DJ Pharma and its 300 person sales force in the US was purchased and in December 2000 the Cardizem family of products was acquired from Aventis.

In 1997 Biovail sponsored the establishment of Intelligent Polymers Limited, an R&D vehicle, that contracted with Biovail to develop several controlled release products. This vehicle, which was purchased in 2000 by Biovail, is the source for Biovail's near term product pipeline. Now Biovail is sponsoring the establishment of the FlashDoseCo R&D vehicle for its mid-term product pipeline.

FlashDoseCo

Pharmaceutical Technologies Limited ("FlashDose Co" or "PTL") will be a newly formed Bermuda exempted company owned by third parties (the "Equity Investors").

FlashDoseCo will raise debt financing that will provide it with the capital to complete the R&D programs for the application of Biovail's Flash Dose ("FD") technology to a basket of four products and to conduct clinical research trials on controlled release ("CR") products. FlashDoseCo will have the right to develop other products currently under Biovail's R&D program should pre-determined milestones not be achieved. Biovail will provide FlashDoseCo with strategic advice under the Advisory Agreement and may provide FlashDoseCo with product development services.

It is contemplated that Biovail will market and manufacture the products on completion of their development. FlashDoseCo will be entitled to royalties from the net sale of the products by Biovail or its licensees. Biovail will have an option to terminate FlashDoseCo's royalty entitlement on payment of amounts to be negotiated prior to closing. Biovail will also have the right to acquire the shares in FlashDoseCo from the Equity Investor.

The products to be developed by FlashDoseCo represent 6 significant products under development in Biovail's mid-term drug pipeline. The drugs to be developed by FlashDoseCo include two products aimed at different segments of the \$3.5 billion pain treatment market, two products for the \$9 billion anti-depressant market, and one sleep disorder product, and one product in the \$1.7 billion general anxiety disorder market.

The table below summarizes the products to be developed by FlashDoseCo, the technology to be applied - FD, CR, or both FD and CR, the budgeted expenditures, the targeted launch date and the projected stabilized sales level.

Product Overview

(USD Millions)

<u>Current Status</u>	<u>Branded Product</u>	<u>Technology</u>	<u>Indication</u>	<u>R&D Budget</u>	<u>Targeted Approval Date</u>	<u>Target Launch</u>	<u>Current Branded Revenue</u>	<u>Target Biovail Revenue</u>
Phase III	Bupirone	CR	Anti-Anxiety	\$7	Q3/03	Q3/03	\$700	\$500
Scale Up	Fluoxetine	FD	Depression	\$4	Q1/03	Q1/03	\$2,350	\$350
Phase I	Oxycodone	FD/CR	Pain	\$20	Q2/05	Q4/06	\$1,200	\$760
Phase I	Paroxetine	FD	Depression and Anxiety	\$5	Q2/03	Q3/04	\$1,650	\$240
Phase III	Tramadol	CR	Pain	\$35	Q3/05	Q1/05	\$ 500	\$210
Phase I	Zolpidem	FD/CR	Sleep disorders	\$11	Q4/03	Q4/06	\$ 700	\$130
					Q2/04	Q4/06		
Allocated				\$82			\$7,100	\$1,190
Unallocated				\$11				
Total R&D				\$93				
General				\$37				
Interest and								
Other (net)								
Total Costs				\$130				

Source: IMS LTM DLO/2000

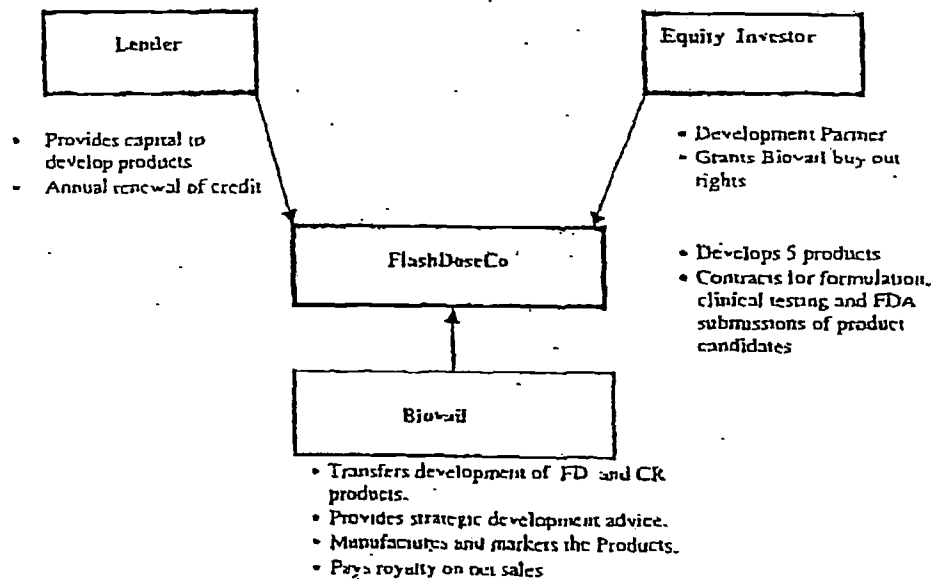
Biovail intends to launch these products when any applicable patents to the innovator drugs have expired. Biovail may alternatively out-license its Flash Dose technology application to the branded product to its innovator. This second approach would allow Biovail earlier direct access to the market as it would preclude any patent expiry issues, and would allow the innovator to extend its brand exclusivity.

In addition, FlashDoseCo will acquire and install \$10 million of equipment to scale-up Flash Dose production in Biovail's Puerto Rico production facility, resulting in a total funding requirement for FlashDoseCo over three years of \$140MM.

FlashDoseCo will fund all development expenses on the products from January 1, 2001 and the transaction is to close prior to June 30, 2001.

2. Transaction Summary

- Equity Investor to invest \$1MM in capital of FlashDoseCo
- FlashDoseCo will raise \$130MM in capital for its R&D program in three annual tranches of \$60MM, \$40MM and \$30MM.
- FlashDoseCo will complete the research and development programs for a portfolio of Flash Dose products and controlled release products under an exclusive technology license arrangement with Biovail to apply its Controlled-Release and Flash Dose technologies to certain products. Biovail will retain ownership of the underlying Controlled Release and Flash Dose technologies.
- Biovail will provide FlashDoseCo with strategic development advice on its R&D program
- FlashDoseCo will contract with third parties, and potentially with Biovail affiliates, to conduct the research and development program. Biovail will have first right of refusal on the development of these products.
- FlashDoseCo will acquire and install \$10MM of production equipment in Biovail's Dorado, Puerto Rico facility and lease that equipment to Biovail. Biovail will hold an option to purchase the equipment from FlashDoseCo
- Biovail and/or its licensees will manufacture and market the approved drugs
- FlashDoseCo will earn royalties from the net sale of the products by Biovail and/or its licensees
- Biovail will hold a purchase option to buy out FlashDoseCo's entitlement to the Royalties in return for payment of specified amounts, and an option to purchase its shares from the Equity Investor.



3. Summary of Terms and Conditions

June 8, 2001

PROJECT FLASHDOSE

SUMMARY OF TERMS AND CONDITIONS

The following is intended as a summary outline of the principal terms and conditions which will govern the proposed structure and financing of FlashDoseCo and which will be set forth in one or more definitive transaction agreements.

FLASHDOSECO

FlashDoseCo, a newly incorporated corporation to be formed under the laws of . The directors of FlashDoseCo will be appointed by the Equity Investor (as defined below). The voting shares of FlashDoseCo will be owned by the Equity Investor.

FlashDoseCo will contract with BLI to complete the research and development program ("R&D Program") for the application of the FlashDose technology (the "FD Technology") to four products and the completion of the application of BLI's Controlled Release technology (the "CR Technology") to one other product (namely, Tramadol).

FlashDoseCo will contract with . to provide FlashDoseCo with executive, financial, management and administrative services.

Biovail Corporation

Biovail Laboratories Inc.

BIOVAIL

BLI

EQUITY INVESTOR

LENDER

EQUITY COMMITMENT

For an aggregate investment of \$. FlashDoseCo will issue . shares to the Equity Investor as FlashDoseCo's initial capitalization.

DEBT COMMITMENT

In addition, FlashDoseCo will enter into a credit facility with (or issue debt instruments to) the Lender in the amount of approximately \$140 million for purposes of the funding of the R&D Expenditures and the purchase and installation of the Equipment (as defined below).

TERM OF DEBT / ANNUAL REVIEW

Biovail and BLI will make appropriate personnel and information available to FlashDoseCo to assist it in its initial negotiations with the Lender.

It is anticipated that the terms of FlashDoseCo's debt will provide for an annual review by the Lender of the progress of the R&D Program. Biovail and BLI will also make appropriate personnel and information available to FlashDoseCo to assist it with the annual credit review discussions with the Lender.

ROYALTY DEVELOPMENT AGREEMENT

In the Royalty Development Agreement, BLI will grant FlashDoseCo a non-assignable (other than to its lender as security) license to its FD Technology and CR Technology (collectively the "Technology"), exclusively for the R&D Program. FlashDoseCo will be entitled to earn a royalty from BLI from the sale of the products to which the Technology has been applied (the "Products") by BLI or its licensees for a period of 10 years from the launch of each Product. The Royalty will be at the rate of 5, 7 and 10% of Net Sales of the Products (for years 1 and 2, years 3 and 4, and years 5 through 10, respectively) and 20% of royalties earned by BLI on an out-licensing of a Product from the launch of each Product. BLI or its licensees shall manufacture and market the Products.

To the extent possible, BLI will assign, or cause to be assigned, to FlashDoseCo all existing clinical and developmental contracts in respect of the current development of the Products and the Technology as it applies to the Products.

The transaction will include a product liability indemnity in favour of FlashDoseCo, that is consistent with industry practices.

As part of the R & D Program, FlashDoseCo will agree to complete or cause completion of the research and development work (including PK studies and Phase III and IV studies) and will incur the costs (the "R&D Expenditures") to be expended for the application of the Technology to the Products for a three year period.

FlashDoseCo may, at its option, on 30 days' written notice to BLI, exercise its right to cease to incur any further R&D Expenditures, if either of the following events occurs:

- a) FlashDoseCo determines that the net present value of the expected future royalty stream under the Royalty Development Agreement is less than the estimated cost required to be incurred to commercialize the Products, or

- b) FlashDoseCo determines that BLI will not have the financial capacity to commercialize the Products upon the completion of FlashDoseCo's development of the Products

The initial budget for the R & D Expenditures for each Product (the "R & D Budget") will be attached as a schedule to the Royalty Development Agreement. A revised R & D Budget will be reviewed and agreed to by FlashDoseCo and BLI at least once every six months

TRAMADOL CR OPTION

In the Royalty Development Agreement, BLI will be granted an option (the "Tramadol CR Option") exercisable on 30 days' notice to terminate FlashDoseCo's development of Tramadol CR under the Royalty Development Agreement at any time and from time to time.

The exercise price for the Tramadol CR Option from time to time shall be an amount equal to the greater of (i) excess of the net present value of FlashDoseCo's expected royalty stream from the sale of Tramadol CR under the Royalty Development Agreement, over the net present value of the R & D Expenditures forecast in the most recent R & D Budget for Tramadol CR (as provided for above under "Royalty Development Agreement"), and (ii) \$25 million. For the purposes of determining the amount in (i) above, the net present value of the expected future royalties at each quarter-end, and the net present value of the forecast R & D Expenditures as of the date hereof are as set out on Appendix A hereto. The amounts shown on Appendix A for the expected future royalties will be revised from time to time using the same discount rate and methodology and the R & D Expenditures will be updated to reflect the most recent R & D Budget as described above

SUBSTITUTION RIGHTS

FlashDoseCo will be entitled to perform the R&D Program related to the application of FD Technology to up to two additional products (which shall be included as "Products" under the Royalty Development Agreement) in the event that all of the initial Products are reasonably determined to be no longer commercially feasible, as described in (c) under "Royalty Development Agreement" above or if the product development and commercialization milestones described in (a) and (b) under "Events of Termination" (see below) are not achieved

FLASHDOSECO COVENANT

During the term of the relevant agreements, FlashDoseCo will not sell, transfer, license or otherwise dispose of its interest (or any part thereof) in the Royalty Development Agreement without BLI's consent to any party other than to BLI or an affiliate of BLI.

FlashDoseCo will be subject to certain restrictive covenants with respect to its assets and corporate actions. The restrictions will include the payment of dividends, corporate restructurings, sale or disposition of material assets, creation of liens on material assets, and the carrying on of other business activities.

ADVISORY AGREEMENT

FlashDoseCo and BLI will also enter into an Advisory Agreement pursuant to which:

- (a) BLI will provide advisory services (the "Services") to FlashDoseCo for the development of the Products;
- (b) the Services will include strategic advice on formulation, clinical development, regulatory strategy and commercial exploitation, and
- (c) BLI will be paid for the provision of the Services at the rate of \$100,000 per quarter, plus out-of-pocket expenses.

PRODUCT DEVELOPMENT AGREEMENTS

FlashDoseCo will enter into one or more Product Development Agreement(s) for the conducting of and/or arrangement for the research and development services for the Products (including formulation and clinical research services) (the "Product Development Services").

Each Product Development Agreement will contain typical change of control, performance and credit default provisions.

Biovail will be granted the first right of offer to provide the Product Development Services under each Product Development Agreement.

PRODUCTION EQUIPMENT

FlashDoseCo will acquire and arrange for the installation of the equipment train (the "Equipment") for the production of the FlashDose Products in BLI's plant in Dorado, Puerto Rico. The estimated cost of the Equipment and related transitional costs is approximately \$10 million. FlashDoseCo will lease the installed Equipment to BLI at the rate of \$* per year.

The equipment train will include a blender, microsphere towers, bead tower, bead coater and a packaging line.

BLI will be granted an option (the "Equipment Purchase Option") to purchase the Equipment from FlashDoseCo at any time and from time to time. The exercise price of the Equipment Purchase Option will be:

During Year 1: \$0

After Year 1: \$0

After Year 2: \$0

After Year 3: \$0

After Year 4: \$0

FlashDoseCo will not sell, transfer, pledge or otherwise dispose of the Equipment during the term of the Equipment Purchase Option.

BLI ROYALTY PURCHASE OPTION

In the Royalty Development Agreement, BLI will be granted an option (the "Royalty Purchase Option") exercisable on 30 days' written notice to terminate FlashDoseCo's entitlement to royalties under the Royalty Development Agreement, at any time and from time to time. The exercise price of the Royalty Purchase Option will be as follows:

Prior to 12/31/02 - \$110 million

Prior to 6/30/03 - \$120 million

Prior to 12/31/03 - \$135 million

Prior to 6/30/04 - \$140 million

Prior to 12/31/04 - \$150 million

Prior to 12/31/05 - \$175 million

Prior to 12/31/06 - \$195 million

The amounts above will be reduced by the amount paid by BLI on exercise of the Transdrol CR Option.

The closing of the exercise of the Royalty Purchase Option will be within 15 days of exercise.

SHARES PURCHASE OPTION

BLI will also be granted an option (the "Shares Purchase Option") exercisable on 30 days' written notice to purchase all of the Equity Investor's shares in FlashDoseCo at any time and from time to time. The exercise price of the Shares Purchase Option will be:

Prior to 12/31/02 - \$1.75 million

Prior to 6/30/03 - \$2 million

Prior to 12/31/03 - \$2.25 million

Prior to 6/30/04 - \$2.5 million

Prior to 12/31/04 - \$3 million

Prior to 12/31/05 - \$4 million

Prior to 12/31/06 - \$5 million

The Equity Investor shall not sell, transfer, pledge or otherwise dispose, directly or indirectly, of its shares in FlashDoseCo during the term of the Shares Purchase Option.

EVENTS OF TERMINATION

Each of the following events shall be a "Termination Event" for purposes hereof

- a) An NDA or ANDA, as applicable, has not been filed for at least one of the Products within two years from the execution of the Advisory Agreement.
- b) If Biocell or BLI has not, within three years from the execution of the Royalty Development Agreement, commercialized at least one Product within one year of that product receiving approval of its NDA or ANDA, as applicable;
- c) If the Lender does not advance further funds to FlashDoseCo after any annual review of the progress of its R&D Program and Biocell is not willing to provide FlashDoseCo with, or arrange financing, on commercially reasonable terms and rates.
- d) A default by Biocell under the terms of any material financing agreement, or
- e) A change in control of Biocell

CONSEQUENCES OF TERMINATION EVENTS

Following the occurrence of a Termination Event, FlashDoseCo may, at its option, terminate the Shares Purchase Option on 30 days' written notice. Immediately after termination of the Shares Purchase Option, FlashDoseCo may, at its option, terminate:

- i) the Royalty Development Agreement,
- ii) the Advisory Agreement; and
- iii) any Product Development Agreement(s) to which BLI (or an affiliate thereof) is a party

The Lender will not enforce any of its recourse rights under the credit facility (or debt instruments) with FlashDoseCo until after the cancellation of the Royalty Repurchase Option and the Shares Purchase Option.

TRAILING ROYALTIES

If FlashDoseCo terminates the agreements, as provided for above under "Consequences of Termination Events", BLI will grant FlashDoseCo a fully vested earned interest in revenues from the Products entitling it to royalties from the future sale of the Products ("Trailing Royalties") at the rate under the Royalty Development Agreement multiplied by the degree of completion (determined by the ratio of expenditures incurred to date relative to the most recent R&D Budget) of the R&D Program for each Product at the time of termination.

BLI shall have the option to terminate the obligation to pay Trailing Royalties on the payment of \$0 to FlashDoseCo.

If FlashDoseCo elects to cease funding R&D Expenditures after either of the events described in paragraph a) or b) under the "Royalty Development Agreement" above, then it shall be entitled to a trailing royalty equal to 50% of the Trailing Royalties described above and such obligations may be terminated by BLI on the payment of \$0 to FlashDoseCo.

COOPERATION

Biovail, BLI, FlashDoseCo and the Equity Investor will cooperate with each other to structure, implement and complete the transactions contemplated herein in an efficient manner (with a view to maximizing transaction costs and structuring the transactions in a tax effective manner).

DOCUMENTATION

This term sheet represents an outline of the basis on which FlashDoseCo, the Equity Investor and the Lender, respectively, will be prepared to provide the Equity Commitment and Debt Commitment (the "Commitments") and enter into the agreements and other arrangements contemplated herein. It is not exhaustive as to the terms and conditions which will govern the Commitments and such agreements and other arrangements contemplated herein and negotiation will be required to finalize the terms and conditions of the transactions and structure.

The arrangements between FlashDoseCo, Biovail, and BLI will be addressed in further detail in a non-binding letter of intent.

The transactions will be effected on the completion of documentation (referred to herein as the "Definitive Documents") including definitive versions of the agreements referred to herein which will contain the terms and conditions set out herein, in addition to customary conditions precedent, representations and warranties.

covenants, events of default, rights of set-off, and indemnity provisions and other terms, conditions and provisions customary for transactions of this kind. The Definitive Documents will be governed by the laws of Ontario.

CONDITIONS PRECEDENT

Without limiting the other terms of this term sheet, any obligation to complete the transactions contemplated herein will be subject to the fulfillment of the following conditions on or prior to the closing date:

- a) Negotiation of financing by FlashDoseCo on commercially reasonable terms;
- b) Completion and execution of the Definitive Documents;
- c) Approval by the boards of directors of Biovail and B.L.I. and
- d) Satisfactory completion of due diligence by the Equity Investor and its lender.

TIMING

The parties expect to execute a detailed non-binding letter of intent by ■ and execute the Definitive Documents by ■.



June 19, 2003

Mr. Stan Hull
Glaxo SmithKline
Sr. Vice-President - US
Five Moore Drive
F2200
Research Triangle Park, NC
27709

Dear Mr. Hull

We are writing with respect to our recent discussions concerning the supply of Wellbutrin XL ("WBXL") by Biovail to GSK. Despite Biovail's repeated requests, GSK has not finalized an order of trade supplies of WBXL from Biovail in Q2, 2003, but has asked Biovail to ship quantities of WBXL for packaging as samples only. GSK took this position only after Biovail had agreed to reduce the price for samples significantly and which therefore produces no net profit for Biovail. This reduction was a major concession made by Biovail to GSK in the spirit of what we expected to be continuing cooperation between our respective companies.

You will recall that, in June of 2002, representatives of Biovail had a meeting with David Stout and yourself of GSK, at which time we discussed Biovail's requirement to ship trade supplies of WBXL to you in Q2 of 2003. We discussed the minimum pricing needed by Biovail for those initial shipments. It was our understanding that we had verbally agreed both on the timing of these shipments and the pricing of the product, so that Biovail could be assured that it could book the revenue associated with these shipments in Q2 of 2003.

We have reiterated our understanding of this agreement, and our need for the forecasts and purchase orders that would implement this agreement, on several occasions at successive meetings and conference calls with you. We discussed this during our last meeting in Philadelphia. At that meeting, Mr. J.P. Gamier expressed the view that Biovail's request was reasonable and he agreed that there should be no downward reconciliation of the invoice price, notwithstanding the wording of the WBXL Agreement.

This is an issue that we have been discussing for over one year. Biovail's understanding of this agreement has been part of Biovail's planning since last June. Because we have not been able to obtain from you either a forecast or a purchase order that would implement the agreement that we thought we had reached, despite the two months that have passed since our last meeting, we have not committed the resources that we would

Biovail Corporation
7150 Mississauga Road
Mississauga, Ontario Canada
L5N 8M5
T 905 286 3000
F 905 286 3050
www.biovail.com

CONFID TRTMNT UNDER FOIA REQ

B 23737

have to commit, (which are otherwise dedicated to the production of Biovail's other products) to produce the quantities of products that would be required to ship both samples and trade supplies in the volumes we had discussed.

Although we have experienced some initial production difficulties, that are the subject of another letter to you, we remain willing, as we have discussed, to produce and sell to you in Q2 all of our current production of WRRL as bulk trade product, which you are entitled to order under the agreement. The pricing, as we have discussed, should be \$12.31 per bottle of 30, 150 mg tablets (252,000 bottles) and \$14.21 per bottle of 30, 300 mg tablets (651,000 bottles), plus \$1.00 for subsequent packaging once the label and package insert is final. (As we have previously agreed, there would be no downward reconciliation of the purchase price that would apply to this initial shipment.)

We expect to be able to fulfill your requirements for samples early in July.

We look forward to our telephone conversation today at 4:00pm EST to discuss this proposal with you, and to receiving confirmation of your acceptance of these terms.

Yours very truly,



Brian Cramble
Sr. VP. & CFO

CC: Eugene Melnyk
Ken Cancellara
Carol Chapuis

Biovail Corporation
7150 Macmillan Road
Mississauga, Ontario Canada
L5N 8M5
www.bivac.com

CONFID TRTMNT UNDER FOIA REQ

B 23738